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(54) **MEDICAL IMPLANT LOCKING MECHANISM**

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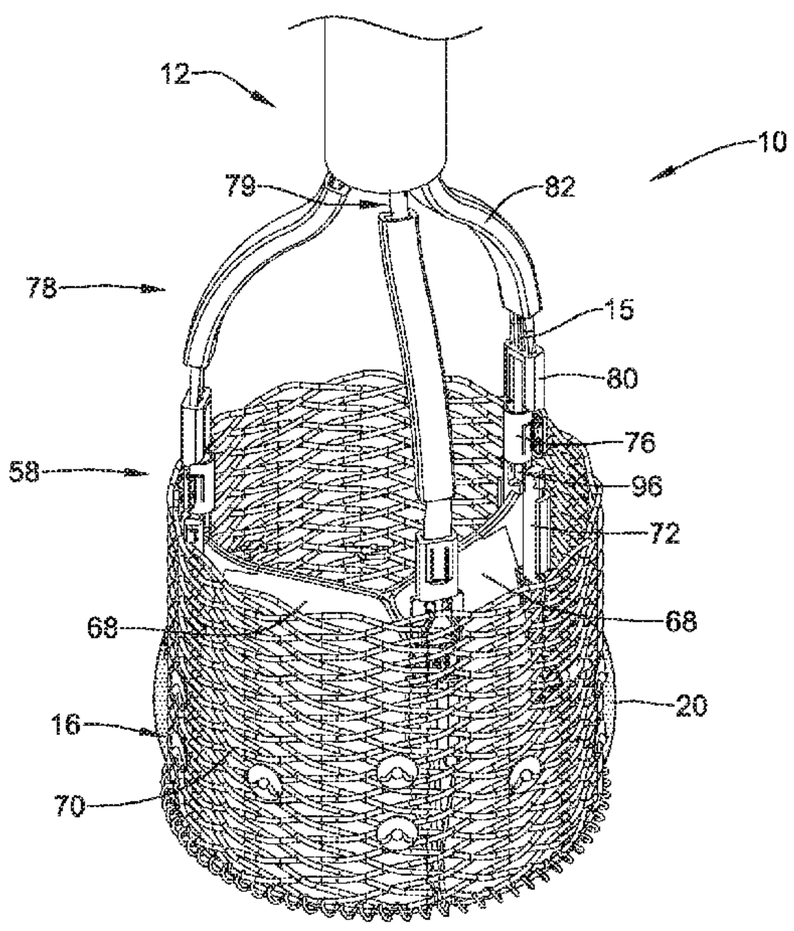
(57) **ABSTRACT**

A medical device system may include a replacement heart valve implant including an expandable anchor member reversibly actuatable between a delivery configuration and a deployed configuration, wherein the replacement heart valve implant includes at least one locking mechanism configured to lock the expandable anchor member in the deployed configuration, and at least one actuator element configured to releasably engage the at least one locking mechanism and actuate the expandable anchor member between the delivery configuration and the deployed configuration. The at least one actuator element may include external threads on a distal portion of each actuator element and a ramp disposed proximal of the external threads.

18 Claims, 13 Drawing Sheets



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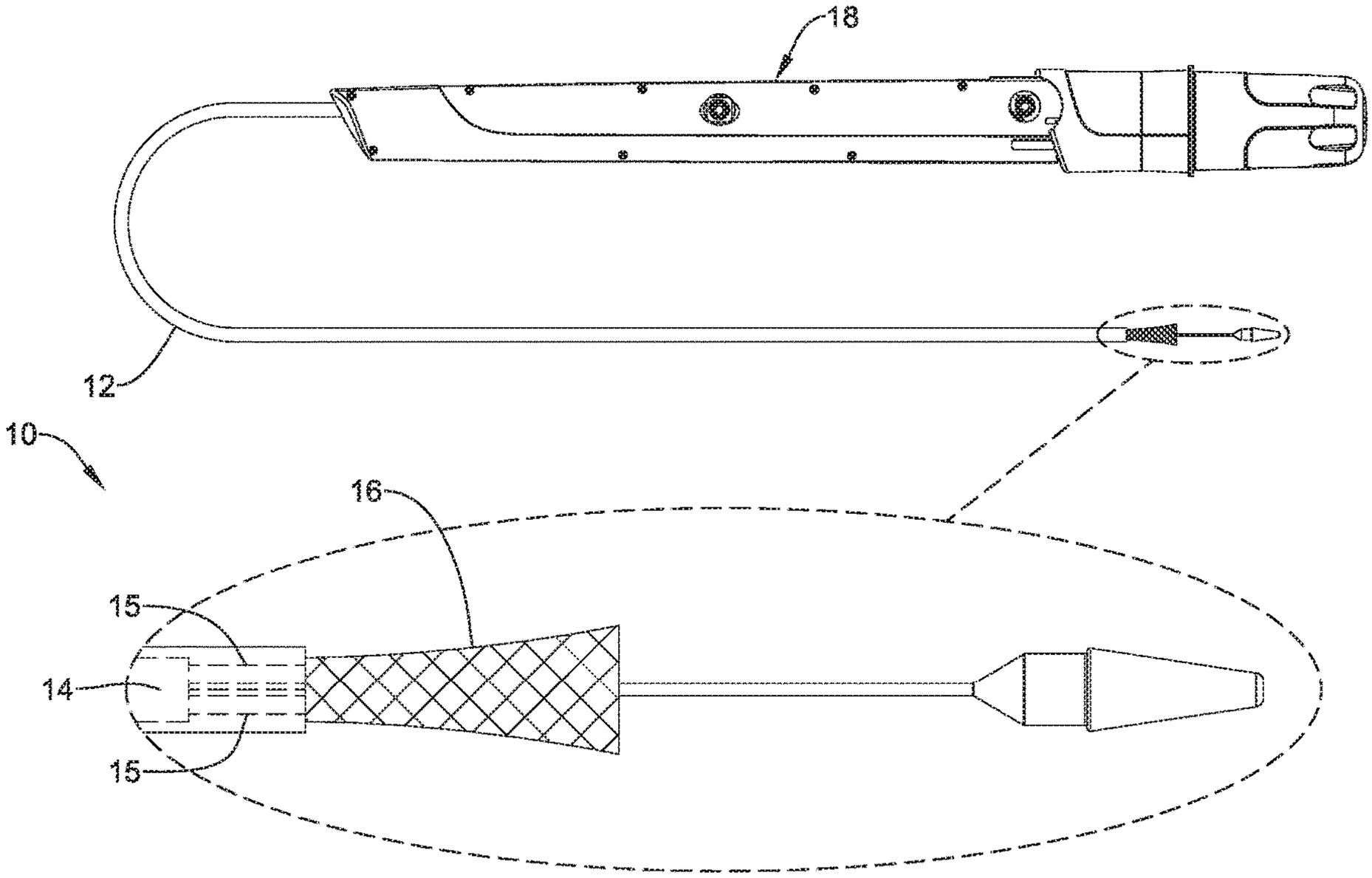

FIG. 1

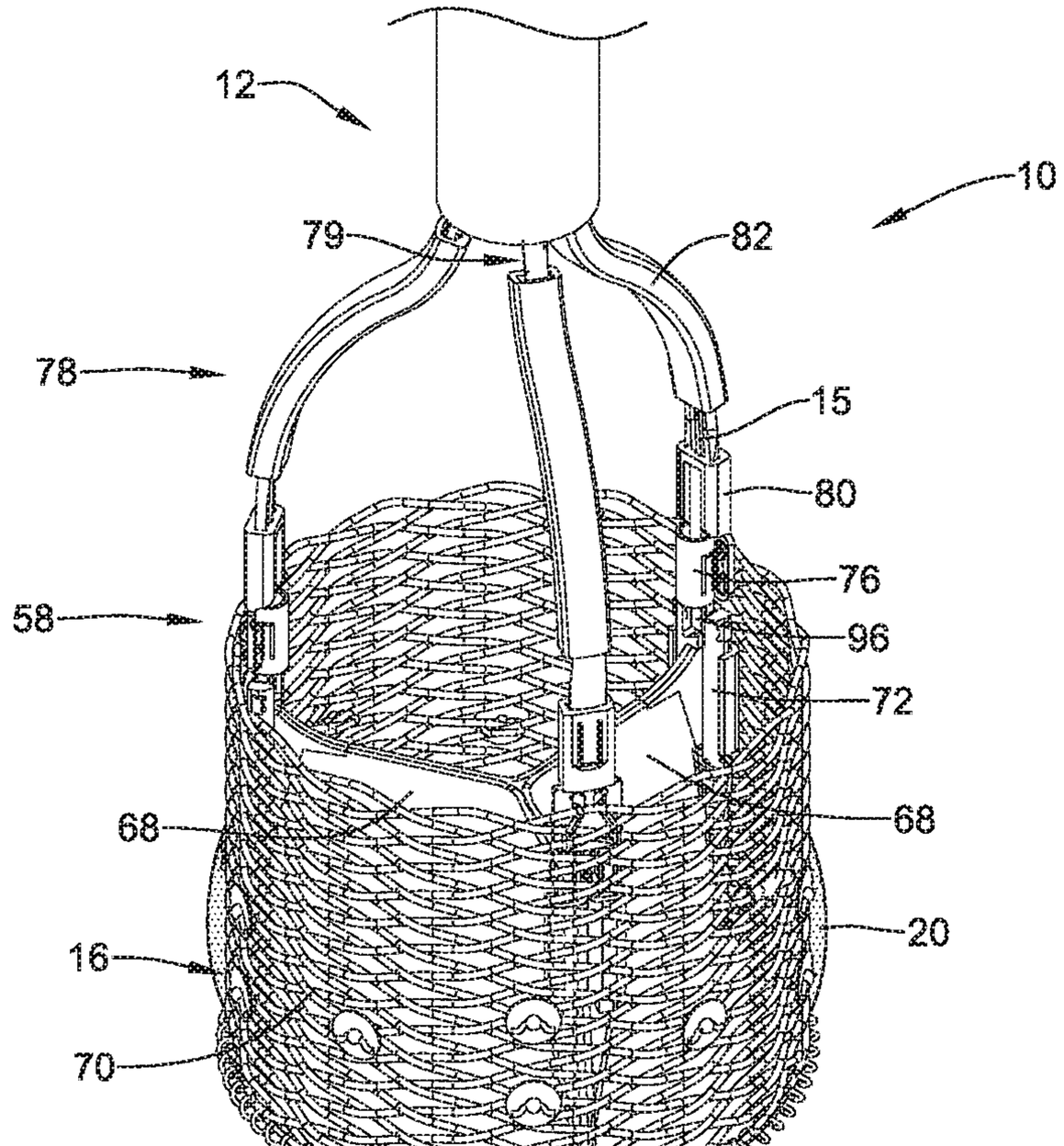

FIG. 2

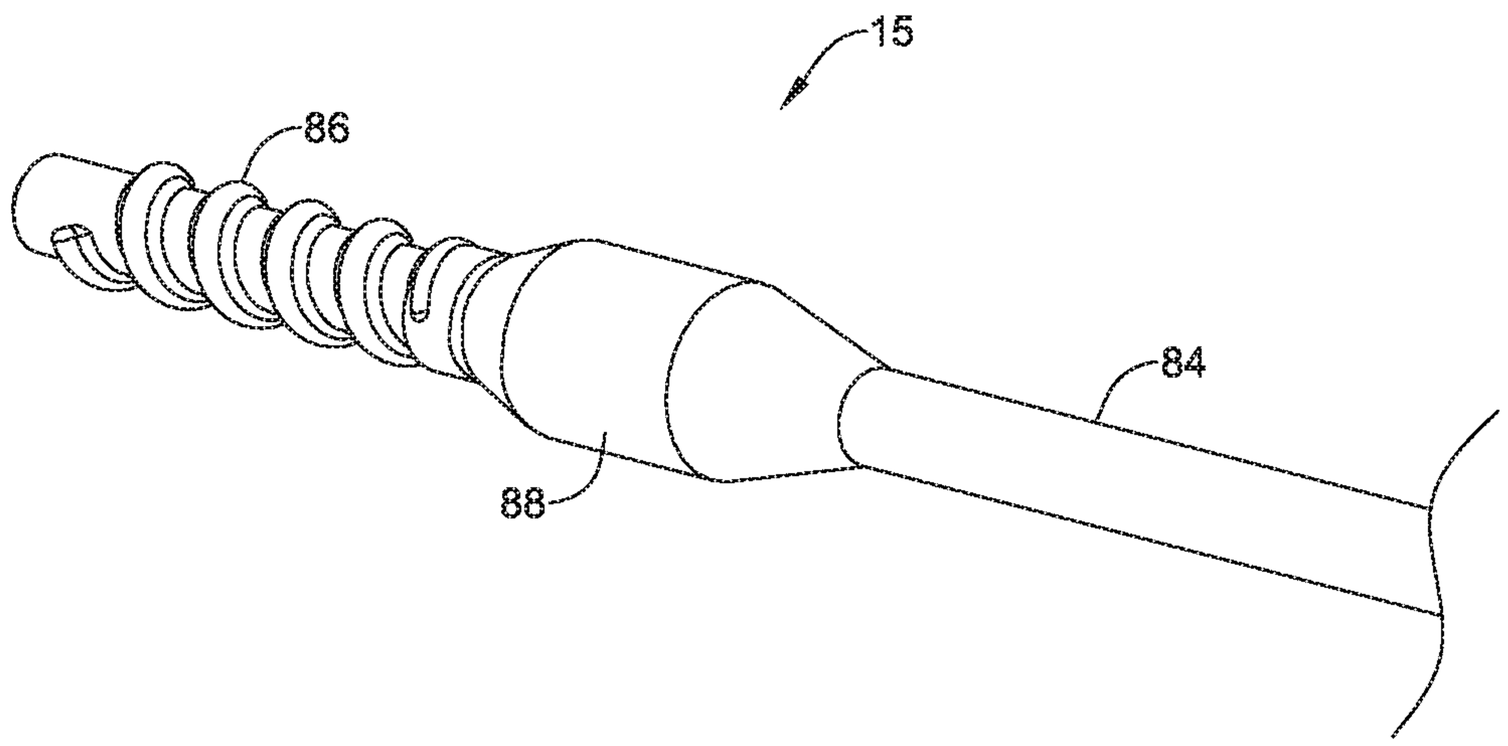

FIG. 3

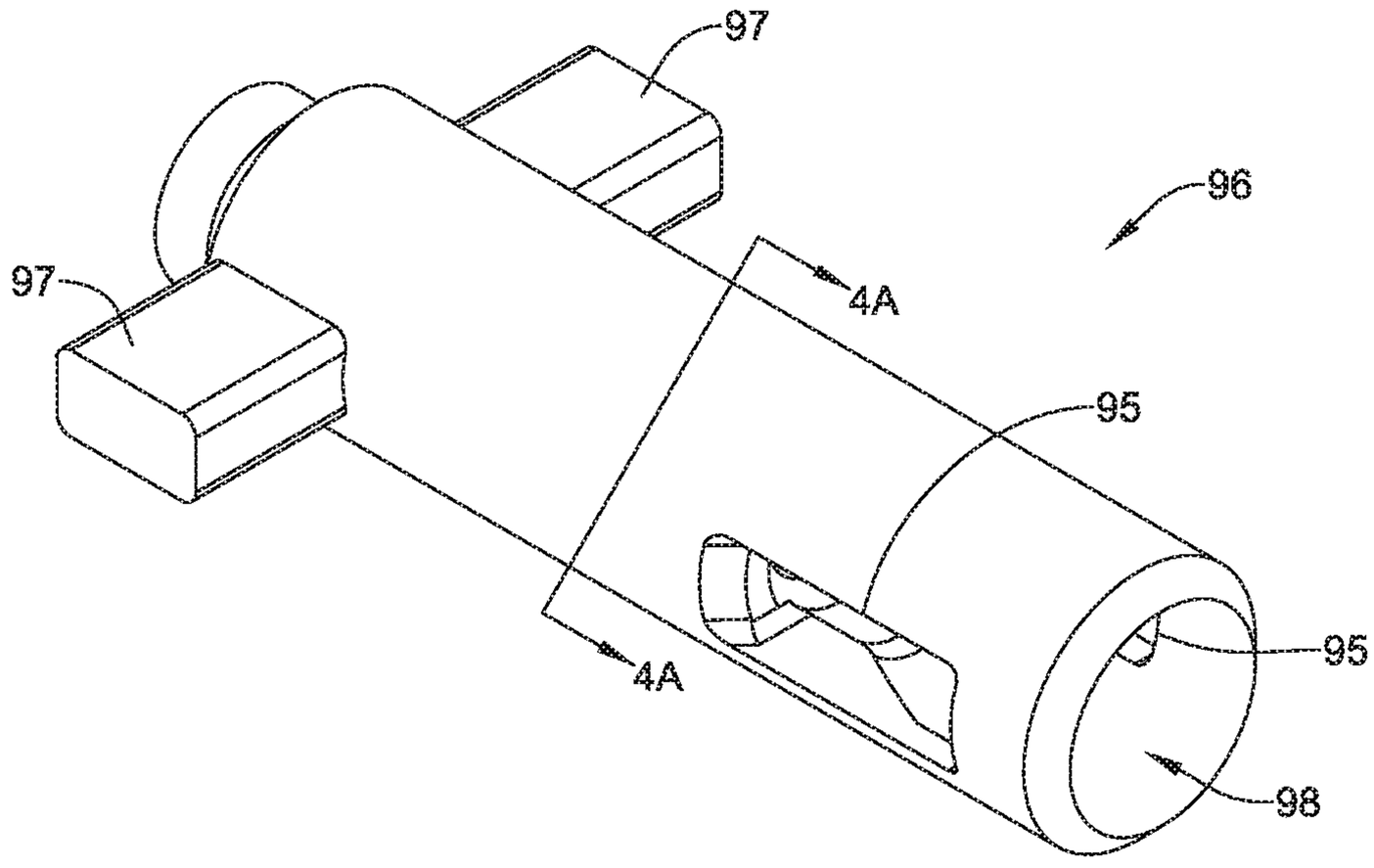

FIG. 4

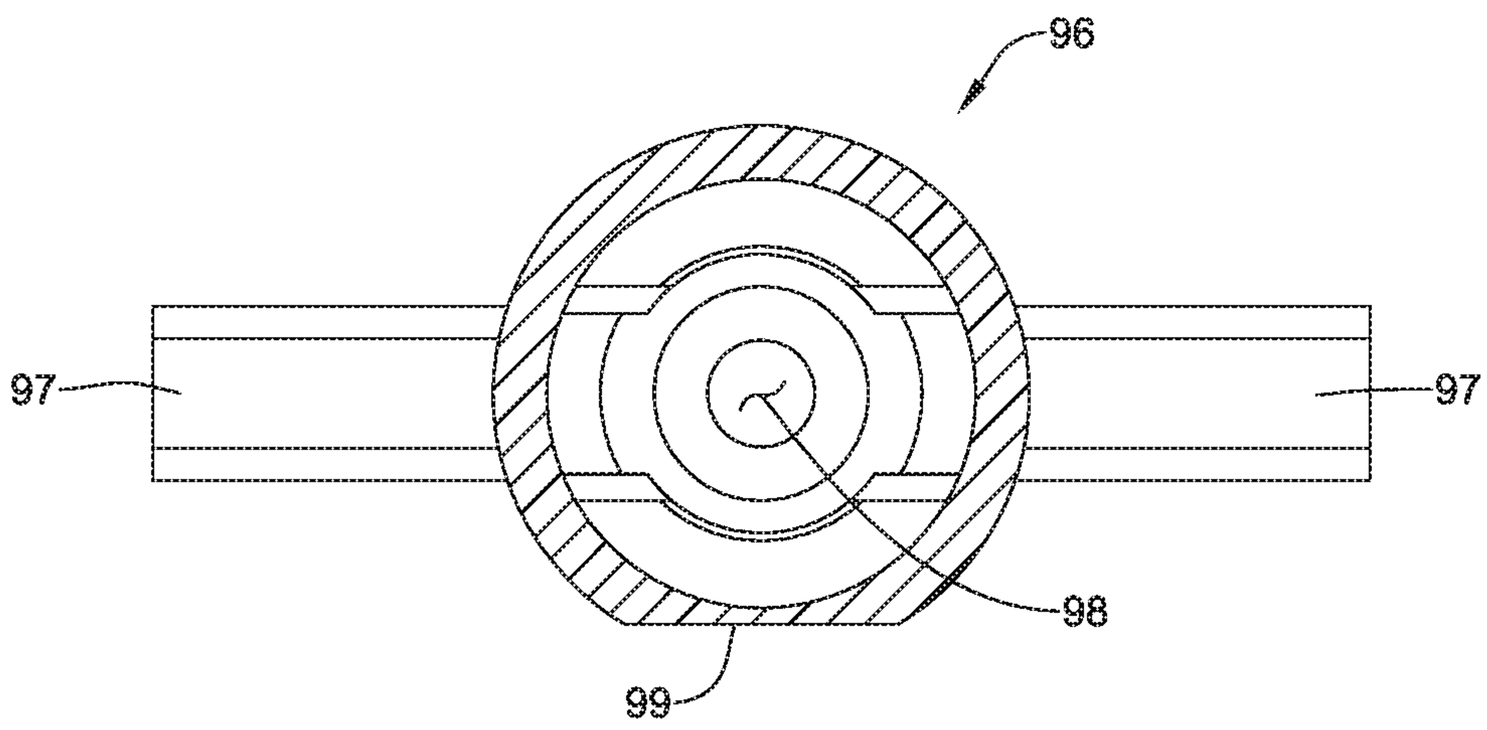

FIG. 4A

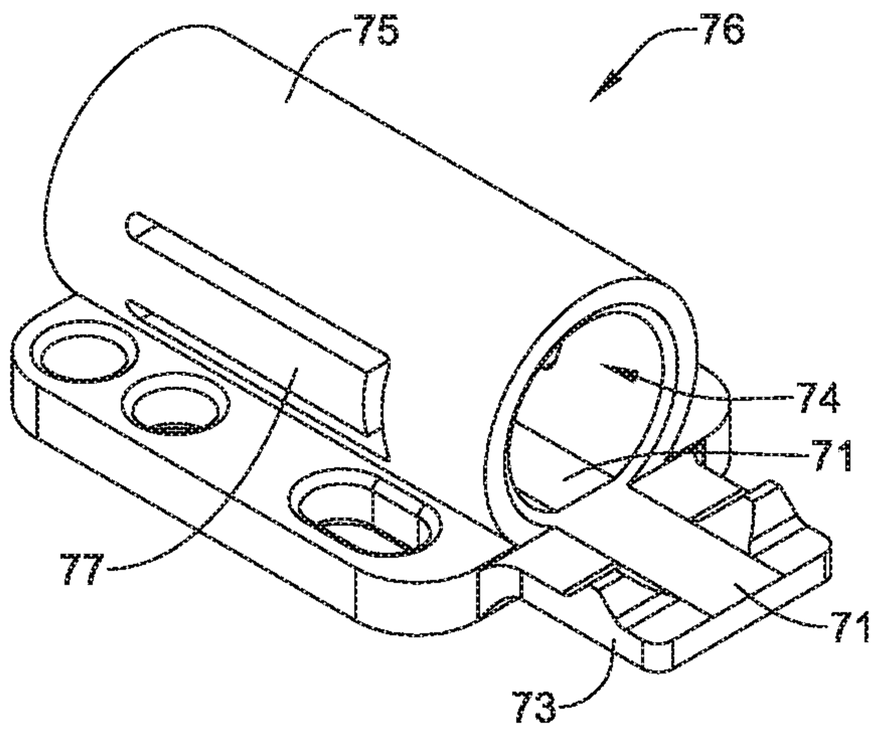

FIG. 5

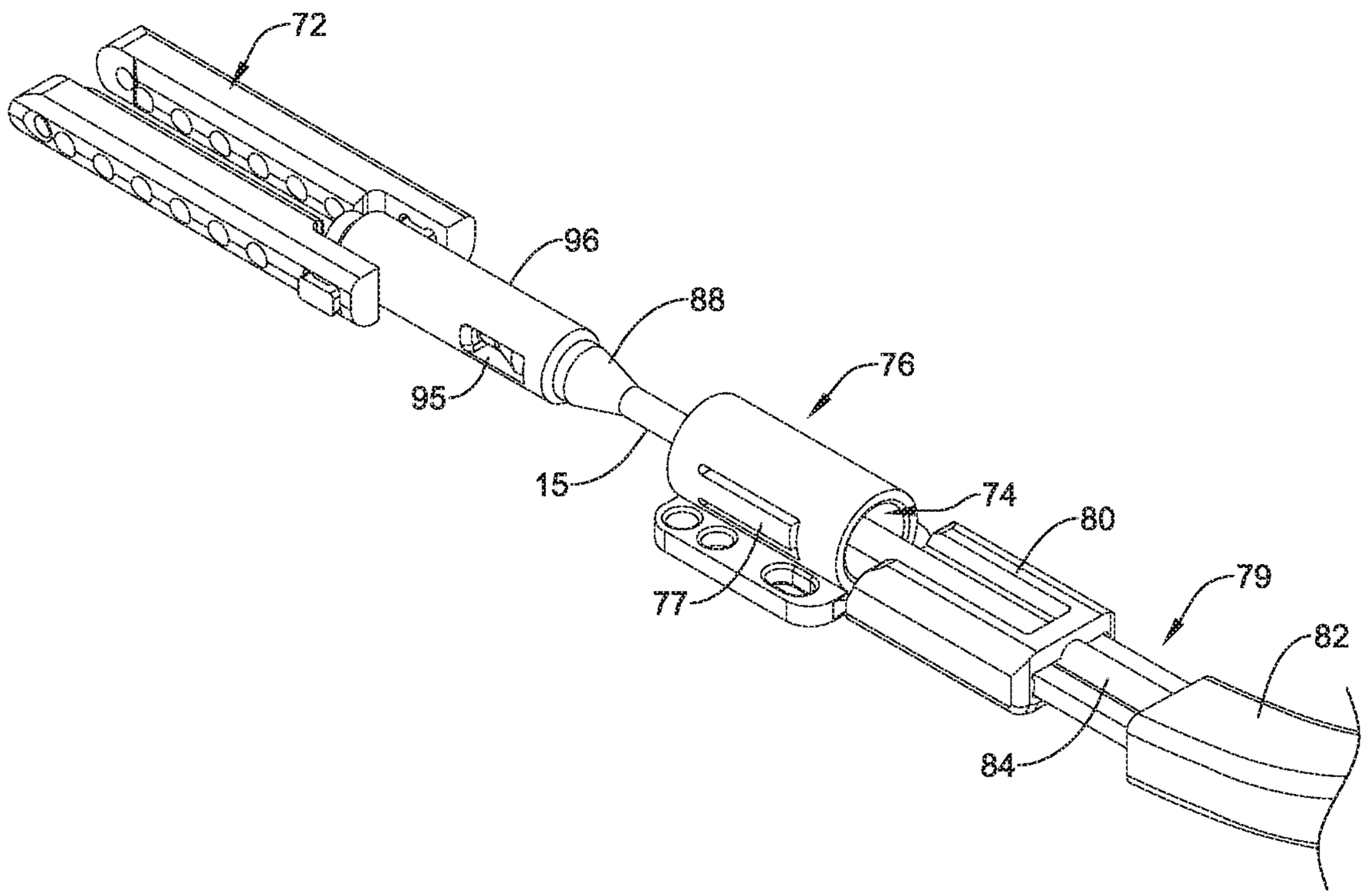

FIG. 6

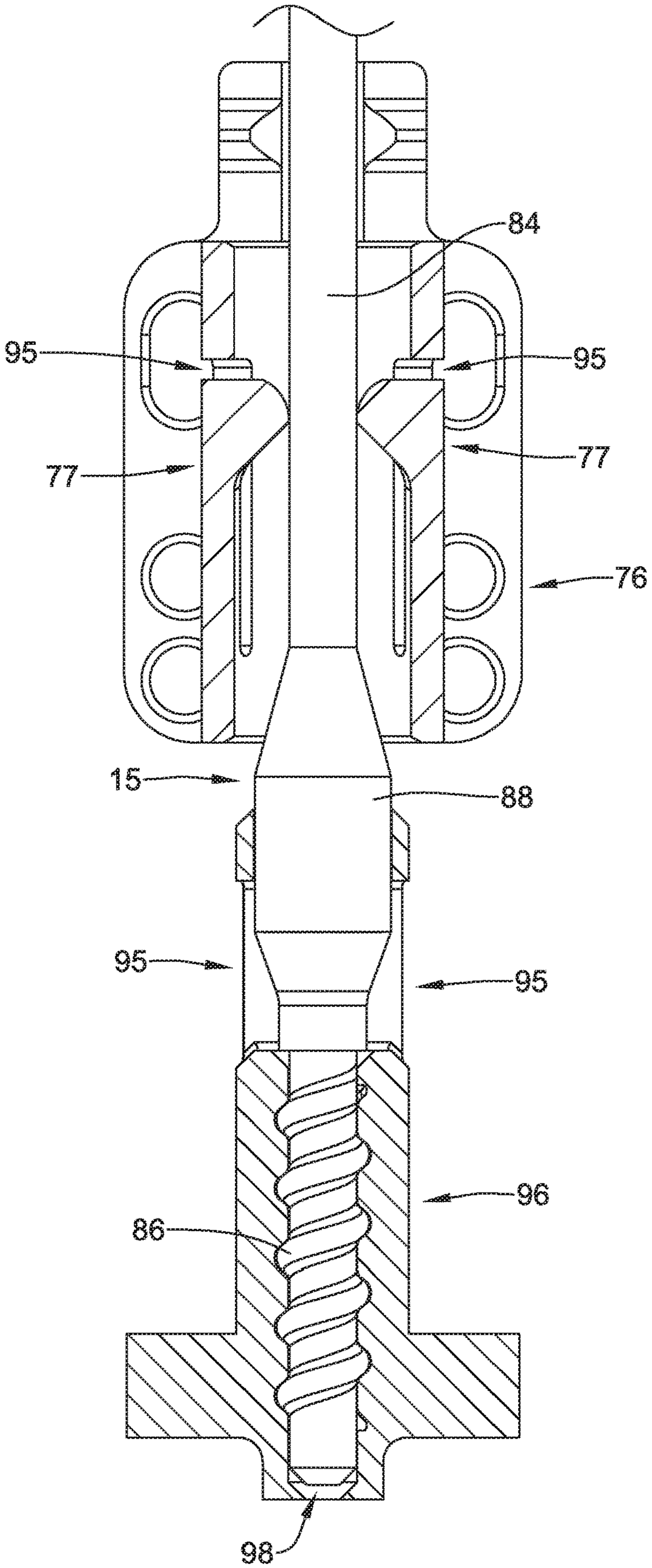

FIG. 7

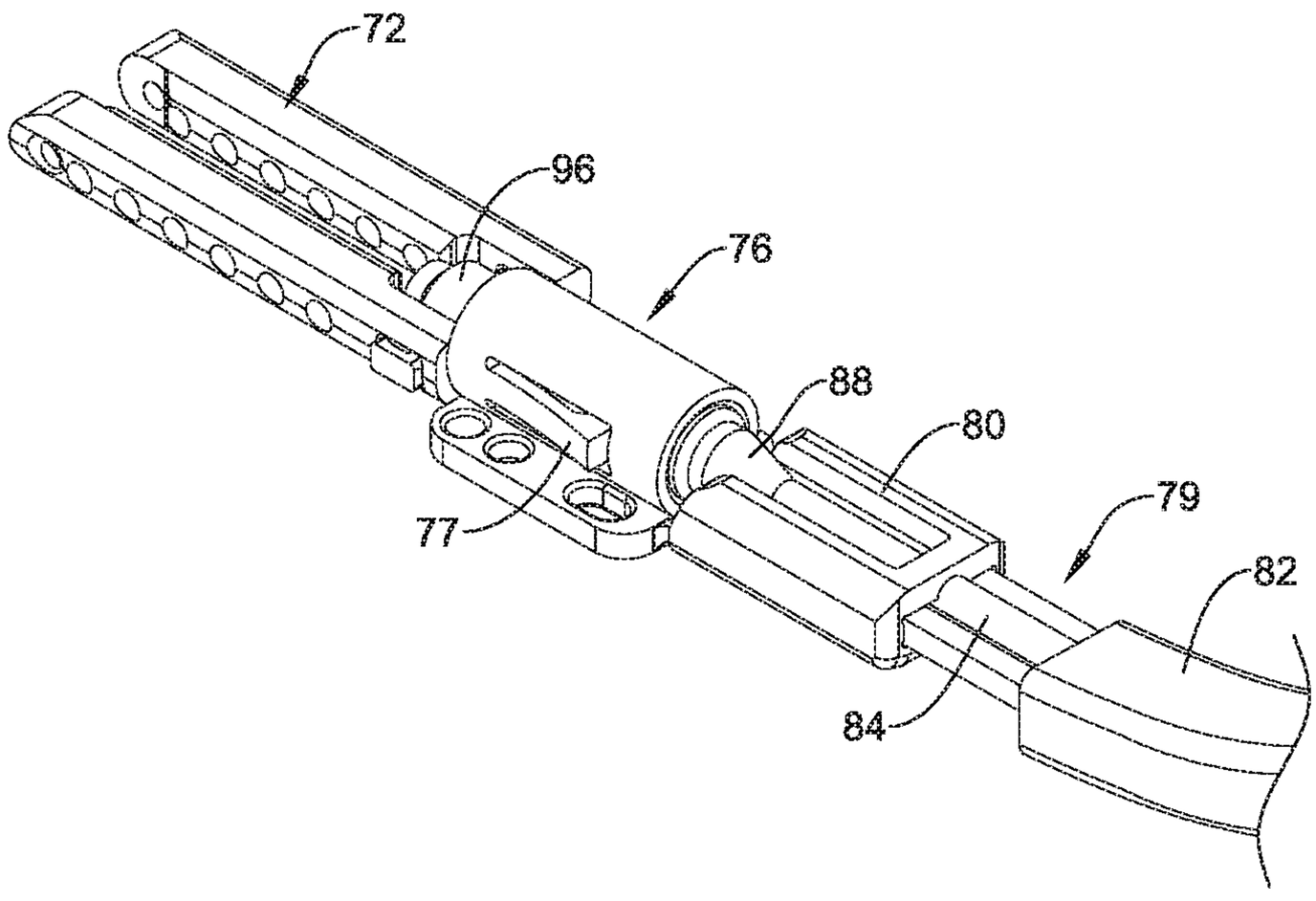

FIG. 8

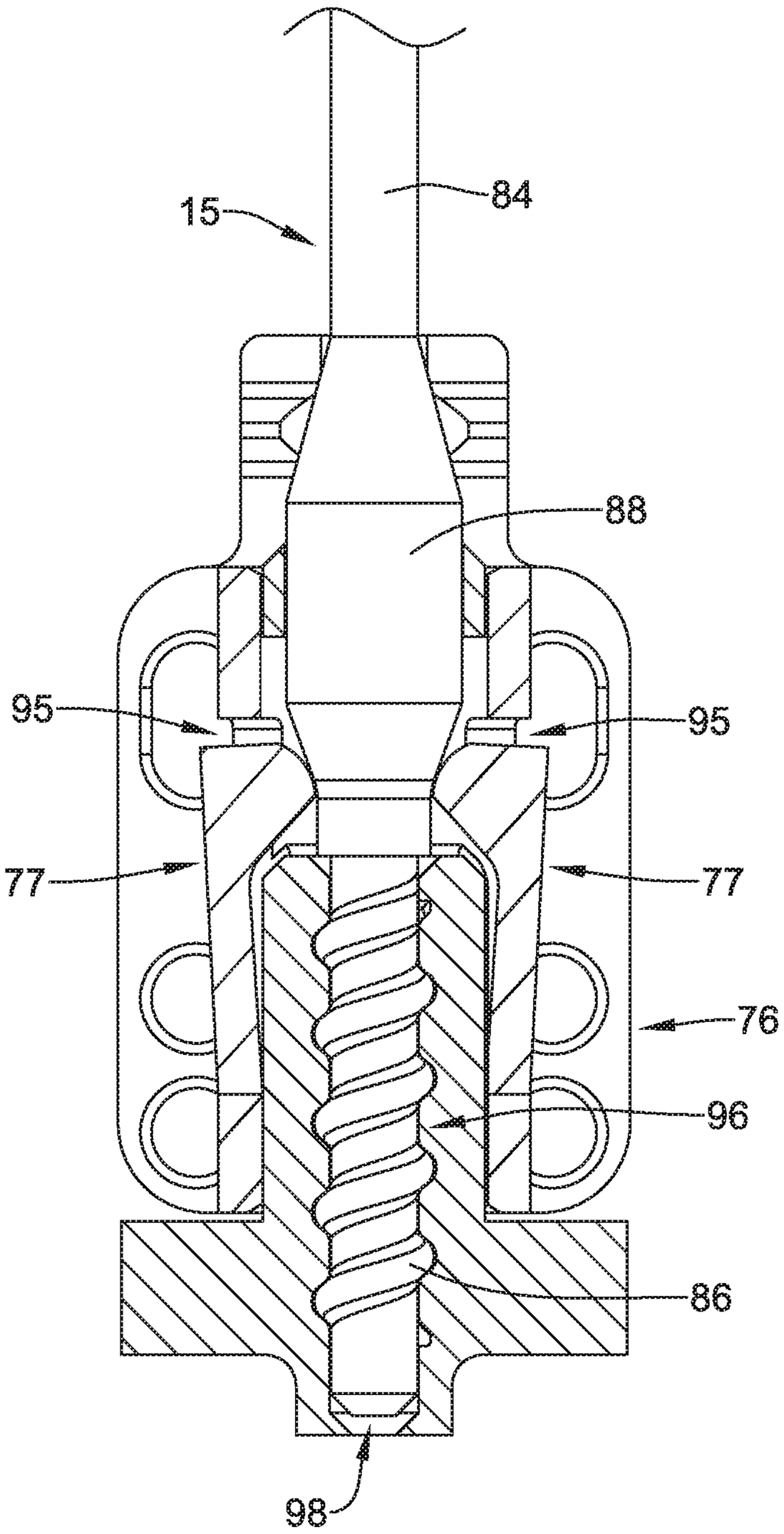

FIG. 9

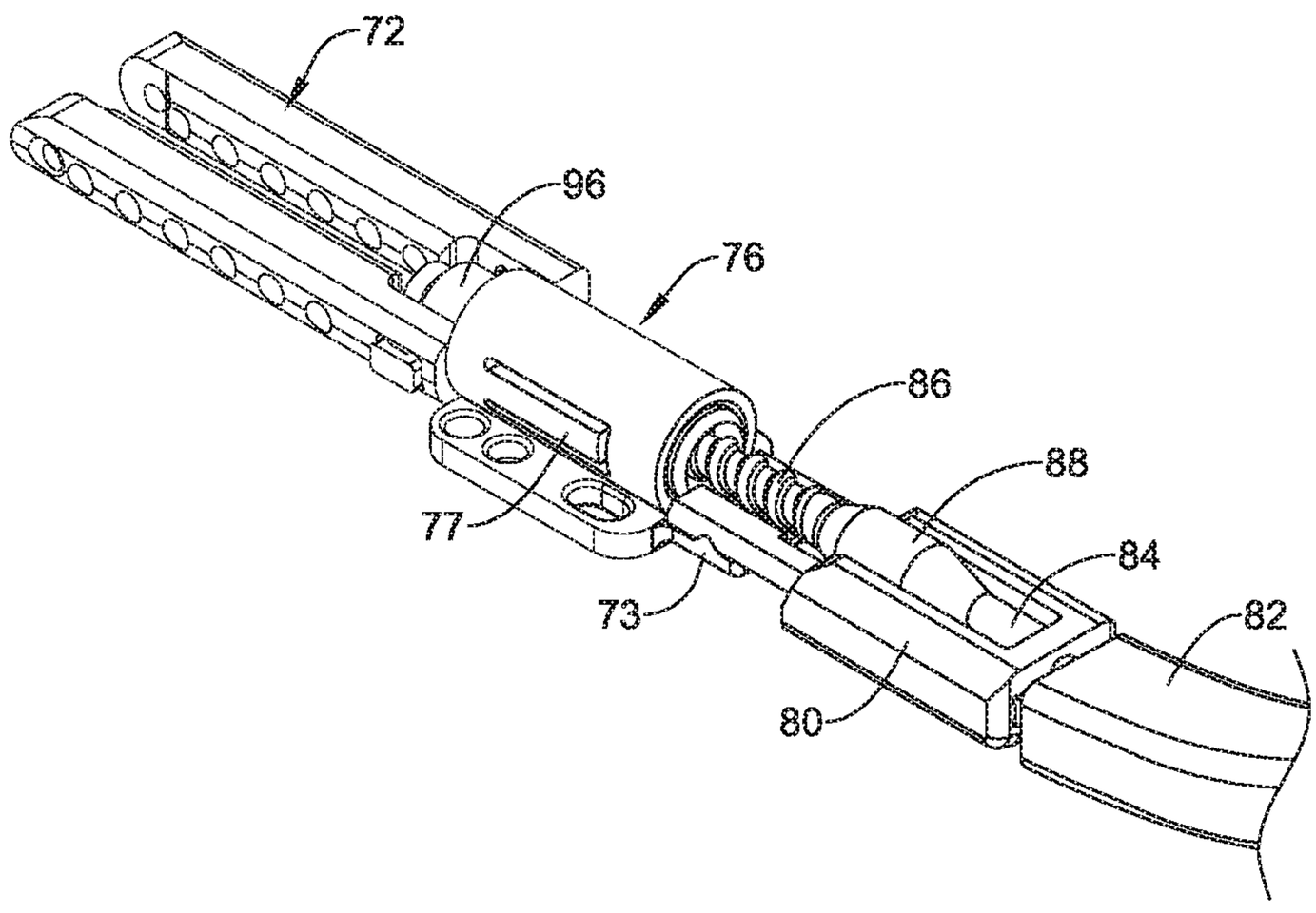

FIG. 10

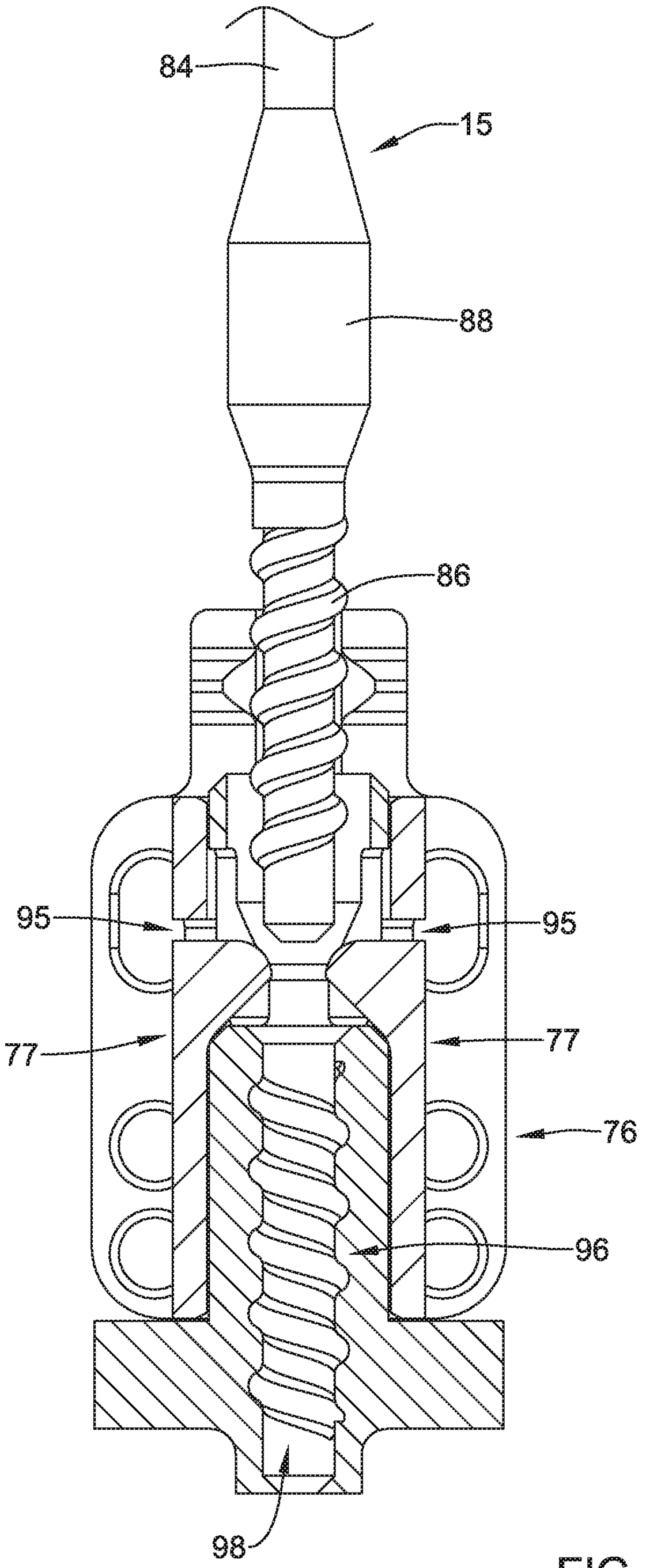

FIG. 11

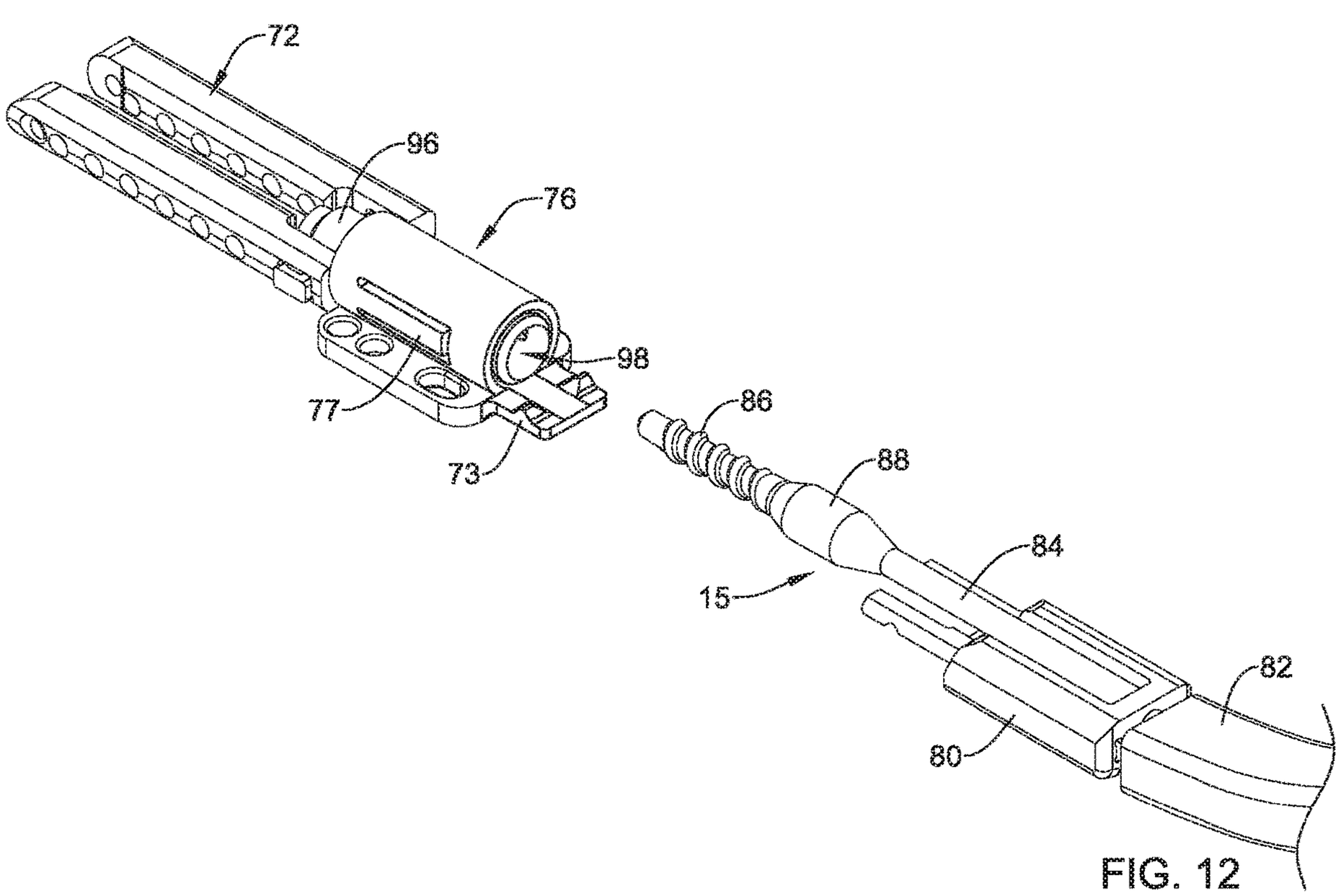

FIG. 12

MEDICAL IMPLANT LOCKING MECHANISM

CROSS-REFERENCE TO RELATED APPLICATIONS

This application claims the benefit of priority under 35 U.S.C. § 119 to U.S. Provisional Application Ser. No. 62/539,717, filed Aug. 1, 2017, the entirety of which is incorporated herein by reference.

TECHNICAL FIELD

The present disclosure pertains to medical devices, and methods for manufacturing and/or using medical devices. More particularly, the present disclosure pertains to locking mechanisms for a medical implant and/or a replacement heart valve.

BACKGROUND

A wide variety of intracorporeal medical devices have been developed for medical use, for example, intravascular use. Some of these devices include guidewires, catheters, medical device delivery systems (e.g., for stents, grafts, replacement valves, etc.), and the like. These devices are manufactured by any one of a variety of different manufacturing methods and may be used according to any one of a variety of methods. Of the known medical devices and methods, each has certain advantages and disadvantages. There is an ongoing need to provide alternative medical devices as well as alternative methods for manufacturing and using medical devices.

SUMMARY

In a first aspect, a medical device system may comprise a replacement heart valve implant including an expandable anchor member reversibly actuatable between a delivery configuration and a deployed configuration, wherein the replacement heart valve implant includes at least one locking mechanism configured to lock the expandable anchor member in the deployed configuration; and at least one actuator element configured to releasably engage the at least one locking mechanism and actuate the expandable anchor member between the delivery configuration and the deployed configuration. The at least one actuator element may include external threads on a distal portion of each actuator element and a ramp disposed proximal of the external threads.

In addition or alternatively, and in a second aspect, the at least one locking mechanism comprises a first locking portion secured to the expandable anchor member and a second locking portion secured to the expandable anchor member, the first locking portion and the second locking portion being longitudinally movable relative to each other in the delivery configuration.

In addition or alternatively, and in a third aspect, the first locking portion is non-releasably secured to a distal portion of the expandable anchor member, and the second locking portion is fixedly secured to a proximal portion of the expandable anchor member.

In addition or alternatively, and in a fourth aspect, the second locking portion is configured to slidably receive the first locking portion within a longitudinal channel extending through the second locking portion.

In addition or alternatively, and in a fifth aspect, the first locking portion is non-rotatable relative to the second locking portion when the first locking portion is at least partially disposed within the longitudinal channel.

In addition or alternatively, and in a sixth aspect, the first locking portion includes a longitudinally-oriented passageway extending at least partially through the first locking portion, the longitudinally-oriented passageway being configured to receive the distal portion of the at least one actuator element.

In addition or alternatively, and in a seventh aspect, the longitudinally-oriented passageway includes internal threads corresponding to the external threads.

In addition or alternatively, and in an eighth aspect, the second locking portion of each of the at least one locking mechanism includes at least one spring arm configured to deflect circumferentially relative to a central longitudinal axis of the expandable anchor member.

In addition or alternatively, and in a ninth aspect, the ramp is configured to deflect each of the at least one spring arm circumferentially as the ramp is longitudinally translated through the second locking portion.

In addition or alternatively, and in a tenth aspect, the first locking portion includes at least one aperture corresponding to each of the at least one spring arm, the at least one aperture extending through the first locking portion at a non-zero angle relative to the central longitudinal axis and being configured to receive a portion of its corresponding spring arm.

In addition or alternatively, and in an eleventh aspect, each of the at least one spring arm is configured to prevent distal movement of the first locking portion relative to the second locking portion after the at least one actuator element has been disengaged from the at least one locking mechanism.

In addition or alternatively, and in a twelfth aspect, a medical device system may comprise an outer sheath; a handle disposed at a proximal end of the outer sheath; a replacement heart valve implant including an expandable anchor member reversibly actuatable between a delivery configuration and a deployed configuration, wherein the replacement heart valve implant includes at least one locking element configured to lock the expandable anchor member in the deployed configuration; and at least one actuator element configured to releasably engage the at least one locking mechanism and actuate the expandable anchor member between the delivery configuration and the deployed configuration. The at least one actuator element may include external threads on a distal portion of each actuator element and a ramp disposed proximal of the external threads. The at least one actuator element may extend from the handle to the replacement heart valve implant, the replacement heart valve implant being disposed at a distal end of the outer sheath.

In addition or alternatively, and in a thirteenth aspect, the at least one actuator element is configured to reversibly actuate the expandable anchor member between the delivery configuration and the deployed configuration while the at least one actuator element is engaged with the at least one locking mechanism.

In addition or alternatively, and in a fourteenth aspect, the handle is configured to rotate each of the at least one actuator element relative to the at least one locking mechanism in the deployed configuration.

In addition or alternatively, and in a fifteenth aspect, rotation of the at least one actuator element relative to the at least one locking mechanism in the deployed configuration

disengages the at least one actuator element from the at least one locking mechanism and releases the replacement heart valve implant.

In addition or alternatively, and in a sixteenth aspect, a medical device system may comprise an outer sheath; a handle disposed at a proximal end of the outer sheath; a replacement heart valve implant including an expandable anchor member reversibly actuatable between a delivery configuration and a deployed configuration, wherein the replacement heart valve implant includes a plurality of locking mechanisms configured to lock the expandable anchor member in the deployed configuration; and a plurality of actuator elements corresponding to the plurality of locking mechanisms, the plurality of actuator elements being configured to releasably engage the plurality of locking mechanisms and actuate the expandable anchor member between the delivery configuration and the deployed configuration. The plurality of actuator elements may include external threads proximate a distal end of each actuator element and a ramp disposed proximal of the external threads. The plurality of actuator elements may extend from the handle to the replacement heart valve implant, the replacement heart valve implant being disposed at a distal end of the outer sheath.

In addition or alternatively, and in a seventeenth aspect, the expandable anchor member is tubular and defines a lumen extending coaxially along a central longitudinal axis of the replacement heart valve implant.

In addition or alternatively, and in an eighteenth aspect, the handle is configured to rotate each of the plurality of actuator elements relative to the outer sheath in the deployed configuration.

In addition or alternatively, and in a nineteenth aspect, each of the plurality of actuator elements defines its own longitudinal actuator axis and is configured to rotate about its own longitudinal actuator axis.

In addition or alternatively, and in a twentieth aspect, the plurality of locking mechanisms each comprise:

a first locking portion secured to the expandable anchor member and having at least one valve leaflet attached to the first locking portion; and

a second locking portion secured to the expandable anchor member;

wherein the actuator element of the plurality of actuator elements corresponding to each of the plurality of locking mechanisms extends longitudinally through the second locking portion of its locking mechanism in the delivery configuration.

the first locking portion and the second locking portion being longitudinally movable relative to each other in the delivery configuration.

The above summary of some embodiments, aspects, and/or examples is not intended to describe each embodiment or every implementation of the present disclosure. The figures and the detailed description which follows more particularly exemplify these embodiments.

BRIEF DESCRIPTION OF THE DRAWINGS

The disclosure may be more completely understood in consideration of the following detailed description of various embodiments in connection with the accompanying drawings, in which:

FIG. **1** illustrates an example medical device system;

FIG. **2** is a perspective view of an example medical implant;

FIG. **3** illustrates an example actuator element;

FIG. **4** illustrates an example post member;

FIG. **4**A is a cross-sectional view of the example post member of FIG. **4** taken at line **4**A-**4**A;

FIG. **5** illustrates an example buckle member;

FIG. **6** illustrates selected components of an example medical implant associated with an example medical device system in a delivery configuration;

FIG. **7** is a partial section view of the selected components of FIG. **6**;

FIG. **8** illustrates selected components of an example medical implant associated with an example medical device system in a deployed configuration;

FIG. **9** is a partial section view of the selected components of FIG. **8**;

FIG. **10** illustrates selected components of an example medical implant associated with an example medical device system transitioning from the deployed configuration to a released configuration;

FIG. **11** is a partial section view of the selected components of FIG. **10**; and

FIG. **12** illustrates selected components of an example medical implant associated with an example medical device system in the released configuration.

While aspects of the disclosure are amenable to various modifications and alternative forms, specifics thereof have been shown by way of example in the drawings and will be described in detail. It should be understood, however, that the intention is not to limit aspects of the disclosure to the particular embodiments described. On the contrary, the intention is to cover all modifications, equivalents, and alternatives falling within the spirit and scope of the disclosure.

DETAILED DESCRIPTION

The following description should be read with reference to the drawings, which are not necessarily to scale, wherein like reference numerals indicate like elements throughout the several views. The detailed description and drawings are intended to illustrate but not limit the claimed invention. Those skilled in the art will recognize that the various elements described and/or shown may be arranged in various combinations and configurations without departing from the scope of the disclosure. The detailed description and drawings illustrate example embodiments of the claimed invention.

For the following defined terms, these definitions shall be applied, unless a different definition is given in the claims or elsewhere in this specification.

All numeric values are herein assumed to be modified by the term "about," whether or not explicitly indicated. The term "about", in the context of numeric values, generally refers to a range of numbers that one of skill in the art would consider equivalent to the recited value (e.g., having the same function or result). In many instances, the term "about" may include numbers that are rounded to the nearest significant figure. Other uses of the term "about" (e.g., in a context other than numeric values) may be assumed to have their ordinary and customary definition(s), as understood from and consistent with the context of the specification, unless otherwise specified.

The recitation of numerical ranges by endpoints includes all numbers within that range, including the endpoints (e.g., 1 to 5 includes 1, 1.5, 2, 2.75, 3, 3.80, 4, and 5).

Although some suitable dimensions, ranges, and/or values pertaining to various components, features and/or specifications are disclosed, one of skill in the art, incited by the

present disclosure, would understand desired dimensions, ranges, and/or values may deviate from those expressly disclosed.

As used in this specification and the appended claims, the singular forms "a", "an", and "the" include plural referents unless the content clearly dictates otherwise. As used in this specification and the appended claims, the term "or" is generally employed in its sense including "and/or" unless the content clearly dictates otherwise. It is to be noted that in order to facilitate understanding, certain features of the disclosure may be described in the singular, even though those features may be plural or recurring within the disclosed embodiment(s). Each instance of the features may include and/or be encompassed by the singular disclosure(s), unless expressly stated to the contrary. For simplicity and clarity purposes, not all elements of the disclosed invention are necessarily shown in each figure or discussed in detail below. However, it will be understood that the following discussion may apply equally to any and/or all of the components for which there are more than one, unless explicitly stated to the contrary. Additionally, not all instances of some elements or features may be shown in each figure for clarity.

Relative terms such as "proximal", "distal", "advance", "retract", variants thereof, and the like, may be generally considered with respect to the positioning, direction, and/or operation of various elements relative to a user/operator/manipulator of the device, wherein "proximal" and "retract" indicate or refer to closer to or toward the user and "distal" and "advance" indicate or refer to farther from or away from the user. In some instances, the terms "proximal" and "distal" may be arbitrarily assigned in an effort to facilitate understanding of the disclosure, and such instances will be readily apparent to the skilled artisan. Other relative terms, such as "upstream", "downstream", "inflow", and "outflow" refer to a direction of fluid flow within a lumen, such as a body lumen, a blood vessel, or within a device.

The term "extent" may be understood to mean a greatest measurement of a stated or identified dimension. For example, "outer extent" may be understood to mean a maximum outer dimension, "radial extent" may be understood to mean a maximum radial dimension, "longitudinal extent" may be understood to mean a maximum longitudinal dimension, etc. Each instance of an "extent" may be different (e.g., axial, longitudinal, lateral, radial, circumferential, etc.) and will be apparent to the skilled person from the context of the individual usage. Generally, an "extent" may be considered a greatest possible dimension measured according to the intended usage. In some instances, an "extent" may generally be measured orthogonally within a plane and/or cross-section, but may be, as will be apparent from the particular context, measured differently—such as, but not limited to, angularly, radially, circumferentially (e.g., along an arc), etc.

It is noted that references in the specification to "an embodiment", "some embodiments", "other embodiments", etc., indicate that the embodiment(s) described may include a particular feature, structure, or characteristic, but every embodiment may not necessarily include the particular feature, structure, or characteristic. Moreover, such phrases are not necessarily referring to the same embodiment. Further, when a particular feature, structure, or characteristic is described in connection with an embodiment, it would be within the knowledge of one skilled in the art to effect the particular feature, structure, or characteristic in connection with other embodiments, whether or not explicitly described, unless clearly stated to the contrary. That is, the various individual elements described below, even if not explicitly shown in a particular combination, are nevertheless contemplated as being combinable or arrangeable with each other to form other additional embodiments or to complement and/or enrich the described embodiment(s), as would be understood by one of ordinary skill in the art.

For the purpose of clarity, certain identifying numerical nomenclature (e.g., first, second, third, fourth, etc.) may be used throughout the description and/or claims to name and/or differentiate between various described and/or claimed features. It is to be understood that the numerical nomenclature is not intended to be limiting and is exemplary only. In some embodiments, alterations of and deviations from previously-used numerical nomenclature may be made in the interest of brevity and clarity. That is, a feature identified as a "first" element may later be referred to as a "second" element, a "third" element, etc. or may be omitted entirely, and/or a different feature may be referred to as the "first" element. The meaning and/or designation in each instance will be apparent to the skilled practitioner.

Diseases and/or medical conditions that impact the cardiovascular system are prevalent throughout the world. Traditionally, treatment of the cardiovascular system was often conducted by directly accessing the impacted part of the system. For example, treatment of a blockage in one or more of the coronary arteries was traditionally treated using coronary artery bypass surgery. As can be readily appreciated, such therapies are rather invasive to the patient and require significant recovery times and/or treatments. More recently, less invasive therapies have been developed, for example, where a blocked coronary artery could be accessed and treated via a percutaneous catheter (e.g., angioplasty). Such therapies have gained wide acceptance among patients and clinicians.

Some relatively common medical conditions may include or be the result of inefficiency, ineffectiveness, or complete failure of one or more of the valves within the heart. For example, failure of the aortic valve or the mitral valve can have a serious effect on a human and could lead to serious health condition and/or death if not dealt with properly. Treatment of defective heart valves poses other challenges in that the treatment often requires the repair or outright replacement of the defective valve. Such therapies may be highly invasive to the patient. Disclosed herein are medical devices that may be used for delivering a medical device to a portion of the cardiovascular system in order to diagnose, treat, and/or repair the system. At least some of the medical devices disclosed herein may be used to deliver and implant a replacement heart valve (e.g., a replacement aortic valve, replacement mitral valve, etc.). In addition, the devices disclosed herein may deliver the replacement heart valve percutaneously and, thus, may be much less invasive to the patient. The devices disclosed herein may also provide other desirable features and/or benefits as described below.

The figures illustrate selected components and/or arrangements of a medical device system **10**, shown schematically in FIG. **1** for example. It should be noted that in any given figure, some features of the medical device system **10** may not be shown, or may be shown schematically, for simplicity. Additional details regarding some of the components of the medical device system **10** may be illustrated in other figures in greater detail. A medical device system **10** may be used to deliver and/or deploy a variety of medical devices and/or implants to one or more locations within the anatomy. In at least some embodiments, the medical device system **10** may include a replacement heart valve delivery system (e.g., a replacement aortic valve delivery system) that can be used

for percutaneous delivery of a medical or replacement heart valve implant **16**. This, however, is not intended to be limiting as the medical device system **10** may also be used for other interventions including valve repair, valvuloplasty, and the like, or other similar interventions.

FIG. **1** illustrates the medical device system **10** including the medical or replacement heart valve implant **16** configured to be disposed within a native heart valve (e.g., a mitral valve, an aortic valve, etc.), wherein the medical or replacement heart valve implant **16** may be disposed within a lumen of the medical device system **10** in a delivery configuration for delivery to the native heart valve, where the medical or replacement heart valve implant **16** may be shifted to a deployed configuration. In some embodiments, the medical device system **10** may include an outer sheath **12** having a lumen extending from a proximal portion and/or proximal end of the outer sheath **12** to a distal end of the outer sheath **12**. The medical or replacement heart valve implant **16** may be disposed within the lumen of the outer sheath **12** proximate the distal end of the outer sheath **12** in the delivery configuration. In some embodiments, the medical device system **10** may include a handle **18** disposed proximate and/or at the proximal end of the outer sheath **12**.

The medical device system **10** may include an inner sheath or catheter **14** disposed within the lumen of the outer sheath **12** and/or slidable with respect to the outer sheath **12** within the lumen of the outer sheath **12**. In some embodiments, the handle **18** may be disposed proximate and/or at a proximal end of the inner sheath or catheter **14**. In some embodiments, the inner sheath or catheter **14** may be a tubular structure having one or more lumens extending therethrough, the inner sheath or catheter **14** may be a solid shaft, or the inner sheath or catheter **14** may be a combination thereof. In some embodiments, the medical device system **10** may include at least one actuator element **15** releasably connecting the medical or replacement heart valve implant **16** to the handle **18**. For example, the at least one actuator element **15** may extend from the handle **18** to the medical or replacement heart valve implant **16**, the medical or replacement heart valve implant **16** being disposed at a distal end of the lumen of the outer sheath **12**. The at least one actuator element **15** may extend distally from the inner sheath or catheter **14** to the medical or replacement heart valve implant **16**. In some embodiments, the at least one actuator element **15** may be slidably disposed within and/or may extend slidably through the inner sheath or catheter **14**.

The handle **18** and/or the at least one actuator element **15** may be configured to manipulate the position of the outer sheath **12** relative to the inner sheath or catheter **14** and/or aid in the deployment of the medical or replacement heart valve implant **16**. For example, the inner sheath or catheter **14** and/or the at least one actuator element **15** may be used to move the medical or replacement heart valve implant **16** with respect to the outer sheath **12** of the medical device system **10**. In some embodiments, the inner sheath or catheter **14** and/or the at least one actuator element **15** may be advanced distally within the lumen of the outer sheath **12** to push the medical or replacement heart valve implant **16** out the distal end of the outer sheath **12** and/or the medical device system **10** to deploy the medical or replacement heart valve implant **16** within the native heart valve. Alternatively, the inner sheath or catheter **14** and/or the at least one actuator element **15** may be held in a fixed position relative to the medical or replacement heart valve implant **16** and the outer sheath **12** may be withdrawn proximally relative to the inner sheath or catheter **14**, the at least one actuator element **15**, and/or the medical or replacement heart valve implant **16** to deploy the medical or replacement heart valve implant **16** within the native heart valve. Some examples of suitable but non-limiting materials for the medical device system **10**, the outer sheath **12**, the inner sheath or catheter **14**, the at least one actuator element **15**, the handle **18**, and/or components or elements thereof, are described below.

In some embodiments, the medical device system **10** may include a nose cone disposed at a distal end of a guidewire extension tube, wherein the guidewire extension tube may extend distally from the inner sheath or catheter **14** and/or the outer sheath **12**. In at least some embodiments, the nose cone may be designed to have an atraumatic shape and/or may include a ridge or ledge that is configured to abut a distal end of the outer sheath **12** during delivery of the medical or replacement heart valve implant **16**.

In use, the medical device system **10** may be advanced percutaneously through the vasculature to an area of interest or a target location. For example, the medical device system **10** may be advanced through the vasculature and across the aortic arch to a defective heart valve (e.g., aortic valve, mitral valve, etc.). Alternative approaches to treat a defective heart valve are also contemplated with the medical device system **10**. During delivery, the medical or replacement heart valve implant **16** may be generally disposed in an elongated and low profile "delivery" configuration within the lumen of the outer sheath **12**. Once positioned, the outer sheath **12** may be retracted relative to the medical or replacement heart valve implant **16** to expose the medical or replacement heart valve implant **16**. In at least some embodiments, the medical or replacement heart valve implant **16** may be disposed in an "everted" configuration or a partially-everted configuration while disposed within the lumen of the outer sheath **12** and/or immediately upon exposure after retracting the outer sheath **12**. In some embodiments, the medical or replacement heart valve implant **16** may be everted in the "delivery" configuration. The "everted" configuration may involve at least a portion of the valve leaflets (discussed below) of the medical implant **16** being disposed outside of the expandable anchor member (discussed below) of the medical implant **16** during delivery, thereby permitting a smaller radial profile of the medical implant **16** and the use of a smaller overall profile of the outer sheath **12** and/or the medical device system **10**. In some embodiments, the "delivery" configuration and the "everted" configuration may be substantially similar and/or may be used interchangeably herein.

The medical or replacement heart valve implant **16** may be actuated using the handle **18** and/or the at least one actuator element **15** in order to translate the medical or replacement heart valve implant **16** into a radially expanded and larger profile "deployed" configuration suitable for implantation within the anatomy at the area of interest or the target location. When the medical or replacement heart valve implant **16** is suitably deployed within the anatomy, the outer sheath **12** and/or the medical device system **10** can be removed from the vasculature, leaving the medical or replacement heart valve implant **16** in place in a "released" configuration to function as, for example, a suitable replacement for the native heart valve. In at least some interventions, the medical or replacement heart valve implant **16** may be deployed within the native heart valve (e.g., the native heart valve is left in place and not excised). Alternatively, the native heart valve may be removed and the medical or replacement heart valve implant **16** may be deployed in its place as a replacement.

Disposed within a first lumen of the inner sheath or catheter **14** may be the at least one actuator element **15**, which may be used to actuate and/or translate (e.g., expand and/or elongate) the medical or replacement heart valve implant **16** between the "delivery" configuration and the "deployed" configuration. In some embodiments, the at least one actuator element **15** may include or comprise a plurality of actuator elements **15**, two actuator elements **15**, three actuator elements **15**, four actuator elements **15**, or another suitable or desired number of actuator elements **15**. In some embodiments, each of the at least one actuator element **15** may be disposed within a separate lumen of the inner sheath or catheter **14**. For the purpose of illustration only, the medical device system **10** and the medical or replacement heart valve implant **16** are shown with three actuator elements **15**. In such an example, the three actuator elements **15** may require and/or be disposed within three separate lumens (e.g., a first lumen, a second lumen, and a third lumen) of the inner sheath or catheter **14**.

It is to be noted that in order to facilitate understanding, certain features of the disclosure may be described in the singular, even though those features may be plural or recurring within the disclosed embodiment(s). Each instance of the features may include and/or be encompassed by the singular disclosure(s), unless expressly stated to the contrary. For example, a reference to "the actuator element" may be equally referred to all instances and quantities beyond one of "the at least one actuator element".

FIG. **2** illustrates some selected components of the medical device system **10** and/or the medical or replacement heart valve implant **16**, shown in the "deployed" configuration. The medical or replacement heart valve implant **16** may include an expandable anchor member **70** that is reversibly actuatable between the elongated "delivery" configuration and the radially expanded and/or axially shortened "deployed" configuration. In some embodiments, the expandable anchor member **70** may be tubular and defines a lumen extending coaxially along a central longitudinal axis from a distal or inflow end of the expandable anchor member **70** and/or the medical or replacement heart valve implant **16** to a proximal or outflow end of the expandable anchor member **70** and/or the medical or replacement heart valve implant **16**.

In some embodiments, the expandable anchor member **70** may comprise an expandable stent structure and/or framework. In some embodiments, the expandable anchor member **70** may comprise a self-expanding braided and/or woven mesh structure made up of one or more filaments disposed and/or interwoven circumferentially about the lumen of the expandable anchor member **70** and/or the medical or replacement heart valve implant **16**. Non-self-expanding, mechanically-expandable, and/or assisted self-expanding expandable anchor members are also contemplated. In at least some embodiments, the expandable anchor member **70** may be formed as a unitary structure (e.g., formed from a single filament or strand of wire, cut from a single tubular member, etc.). In some embodiments, the expandable anchor member **70** may define a generally cylindrical outer surface in the deployed configuration. Other configurations are also possible—a cross-section defining a generally elliptical outer surface, for example. Some examples of suitable but non-limiting materials for the medical or replacement heart valve implant **16**, the expandable anchor member **70**, and/or components or elements thereof, are described below.

Also shown in FIG. **2**, but omitted from the other figures in the interest of clarity, the replacement heart valve implant **16** may include a plurality of valve leaflets **68** disposed within the lumen of the medical or replacement heart valve implant **16** and/or the expandable anchor member **70**. In some embodiments, the plurality of valve leaflets **68** may be attached and/or secured to the expandable anchor member **70** at a plurality of locations within the lumen of the medical or replacement heart valve implant **16** and/or the expandable anchor member **70**. In some embodiments, the plurality of valve leaflets **68** may be attached and/or secured to the expandable anchor member **70** using sutures, adhesives, or other suitable means.

In some embodiments, the plurality of valve leaflets **68** may include or comprise two leaflets, three leaflets, four leaflets, etc. as desired. The plurality of valve leaflets **68** of the medical or replacement heart valve implant **16** may be configured to move between an open configuration permitting antegrade fluid flow through the medical or replacement heart valve implant **16** and/or the lumen of the medical or replacement heart valve implant **16** and/or the expandable anchor member **70**, and a closed configuration preventing retrograde fluid flow through the medical or replacement heart valve implant **16** and/or the lumen of the medical or replacement heart valve implant **16** and/or the expandable anchor member **70**. The plurality of valve leaflets **68** may each have a free edge, wherein the free edges of the plurality of valve leaflets **68** coapt within the medical or replacement heart valve implant **16**, the expandable anchor member **70**, and/or the lumen extending through the medical or replacement heart valve implant **16** and/or the expandable anchor member **70** in the closed configuration. Some examples of suitable but non-limiting materials for the plurality of valve leaflets **68** may include bovine pericardial, polymeric materials, or other suitably flexible biocompatible materials.

The plurality of valve leaflets **68** may include a valve leaflet commissure movable from a first longitudinal position within the lumen of the medical or replacement heart valve implant **16** and/or the expandable anchor member **70** relative to the proximal or downstream end in the delivery configuration to a second longitudinal position within the lumen of the medical or replacement heart valve implant **16** and/or the expandable anchor member **70** relative to the proximal or downstream end in the deployed configuration. In some embodiments, the plurality of valve leaflets **68** may include more than one valve leaflet commissure. For example, each adjacent pair of valve leaflets **68** may form and/or define one valve leaflet commissure. Therefore, the number of valve leaflet commissures may be directly related to the number of valve leaflets **68** (e.g., three valve leaflets **68** form and/or define three valve leaflet commissures, two valve leaflets **68** form and/or define two valve leaflet commissures, etc.).

In some embodiments, the medical or replacement heart valve implant **16** may include at least one locking mechanism **58** configured to lock the expandable anchor member **70** in the "deployed" configuration. In some embodiments, the at least one locking mechanism **58** may include or comprise a plurality of locking mechanisms **58**, two locking mechanisms **58**, three locking mechanisms **58**, etc. In some embodiments, each valve leaflet commissure may correspond to and/or include one corresponding locking mechanism **58**. Each locking mechanism **58** may include a first locking portion or a post member **96** secured to the expandable anchor member **70** and configured to engage with a second locking portion or a buckle member **76** secured to the expandable anchor member **70**, as will be described in more detail below.

In some embodiments, at least one actuator element **15** may be configured to releasably engage the at least one

locking mechanism **58** and/or reversibly actuate the expandable anchor member **70** and/or the medical or replacement heart valve implant **16** between the "delivery" configuration and the "deployed" configuration and/or the "released" configuration while the at least one actuator element **15** is engaged with the at least one locking mechanism **58**. In some embodiments, one actuator element **15** may correspond to, engage with, and/or actuate one locking mechanism **58**. In some embodiments, one actuator element **15** may correspond to, engage with, and/or actuate more than one locking mechanism **58**. Other configurations are also contemplated.

In some embodiments, the first locking portion or post member **96** and the second locking portion or buckle member **76** may be longitudinally movable relative to each other along an inner surface of the expandable anchor member **70** in the "delivery" configuration and/or between the "delivery" configuration and the "deployed" configuration. In some embodiments, the first locking portion or post member **96** may be non-releasably secured to a distal portion and/or proximate the distal or upstream end of the expandable anchor member **70** along the inner surface of the expandable anchor member **70**. In some embodiments, the second locking portion or buckle member **76** may be fixedly secured to a proximal portion and/or proximate the proximal or downstream end of the expandable anchor member **70** against the inner surface of the expandable anchor member **70**. The second locking portion or buckle member **76** may be configured to slidably receive at least a portion of the first locking portion or post member **96** therein.

In some embodiments, the medical or replacement heart valve implant **16** may include a seal member **20** (shown partially cutaway) disposed on and/or around at least a portion of the outer surface of the expandable anchor member **70**. In some embodiments, the seal member **20** may be coupled and/or secured to the expandable anchor member **70** and/or the plurality of valve leaflets **68**. The seal member **20** may be sufficiently flexible and/or pliable to conform to and/or around native valve leaflets and/or the native heart valve in the deployed configuration, thereby sealing an exterior of the medical or replacement heart valve implant **16** and/or the expandable anchor member **70** within and/or against the native heart valve and/or the native valve leaflets and preventing leakage around the medical or replacement heart valve implant **16** and/or the expandable anchor member **70**.

In some embodiments, the seal member **20** may include a plurality of layers of polymeric material. Some suitable polymeric materials may include, but are not necessarily limited to, polycarbonate, polyurethane, polyamide, polyether block amide, polyethylene, polyethylene terephthalate, polypropylene, polyvinylchloride, polytetrafluoroethylene, polysulfone, and copolymers, blends, mixtures or combinations thereof. Other suitable polymeric materials are also contemplated, some of which are discussed below.

FIG. **3** illustrates an example actuator element **15**. In some embodiments, each actuator element **15** may include a proximal end and a distal end. In use, the proximal end may be operatively connected to the handle **18**, and/or manipulated or otherwise actuated by a user using the handle **18**, to reversibly shift the medical or replacement heart valve implant **16** between the "delivery" configuration and the "deployed" configuration, and later the "released" configuration. In some embodiments, the actuator element **15** may be axially translatable and/or rotatable relative to the first locking portion or post member **96** and/or the second locking portion or buckle member **76** of the medical or replacement heart valve implant **16**.

In some embodiments, each actuator element **15** may include an elongated rod **84** having external threads **86** on a distal portion and/or adjacent a distal end, and a ramp **88** disposed on the distal portion proximal of the external threads **86**. In some embodiments, the actuator element **15** and/or the distal portion may be releasably connected and/or coupled to the post member **96**, as discussed below. In some embodiments, the distal portion, the external threads **86**, and/or the ramp **88** may be integrally formed with or as a part of the elongated rod **84** as a single monolithic structure.

Each of the at least one actuator element **15** (e.g., each of the plurality of actuator elements **15**, etc.) defines its own longitudinal actuator axis and is configured to rotate about its own longitudinal actuator axis. In some embodiments, the ramp **88** may extend transversely from and/or radially outward relative to the longitudinal actuator axis of the actuator element **15** such that the ramp **88** has a greater outer diameter or outer extent than the elongated rod **84**. In some embodiments, the distal portion may include more than one ramp **88** extending transversely from and/or radially outward relative to the longitudinal actuator axis of the actuator element **15**. In some embodiments, the actuator element **15** may include a second ramp extending opposite the ramp **88**, or a plurality of ramps spaced circumferentially around the longitudinal actuator axis of the actuator element **15**. In embodiments having a plurality of ramps **88**, the plurality of ramps **88** collectively defines the outer diameter or outer extent of the plurality of ramps **88** with respect to the elongated rod **84**.

In some embodiments, the distal portion of the actuator element **15** may be aligned with and/or releasably coupled to the first locking portion or post member **96**. In some embodiments, the distal portion may be rotatably received within a longitudinally-oriented passageway of the first locking portion or post member **96**, as discussed below. In some embodiments, the external threads **86** may be configured to engage with, be received by, and/or extend into internal threads formed within the first locking portion or post member **96**. The handle **18** may be configured to rotate each of the at least one actuator element **15** (e.g., each of the plurality of actuator elements **15**, etc.) relative to the outer sheath **12**, the medical or replacement heart valve implant **16**, the corresponding locking mechanism(s) **58** (e.g., the at least one locking mechanism **58**, etc.), and/or the first locking portion or post member **96** in the "deployed" configuration.

In some embodiments, each of the at least one actuator element **15** may be operatively connected to a central shaft extending distally from the handle **18** within the inner sheath or catheter **14**. The central shaft may be rotated by the handle **18** and/or a rotation mechanism disposed within the handle **18**. In some embodiments, each of the at least one actuator element **15** may extend distally from the handle **18** within the inner sheath or catheter **14**. Each of the at least one actuator element **15** may be operatively and individually engaged with a central lead screw disposed within the handle **18**. The central lead screw may be configured to rotate each of the at least one actuator element **15**. In at least some embodiments, the central lead screw may be configured to rotate each of the at least one actuator element **15** simultaneously.

In some embodiments, the actuator element **15** and/or the elongated rod **84** may be generally round, oblong, ovoid, rectangular, polygonal (i.e., two-sided, three-sided, four-sided, five-sided, six-sided, etc.) and/or combinations

thereof in shape. Other shapes, both regular and irregular, are also contemplated. In some embodiments, the actuator element **15** may be formed from a single piece of wire, round stock, or other suitable material, as discussed herein. In some embodiments, the actuator element **15** may be formed by further processing the single piece of wire, round stock, or other suitable material, such as by machining, stamping, laser cutting, etc. Some suitable but non-limiting materials for the actuator element **15**, the elongated rod **84**, the distal portion, the external threads **86**, and/or the ramp **88**, for example metallic materials or polymeric materials, are described below.

FIGS. **4** and **4**A illustrate an example first locking portion or post member **96**. In some embodiments, the first locking portion or post member **96** may include an elongated member configured to engage with and/or releasably couple to the distal portion and/or the external threads **86** of the actuator element **15**. In some embodiments, the first locking portion or post member **96** may include a longitudinally-oriented passageway **98** extending at least partially through the first locking portion or post member **96**. In some embodiments, the longitudinally-oriented passageway **98** may extend completely through the first locking portion or post member **96**. In some embodiments, a longitudinal axis of the longitudinally-oriented passageway **98** and/or the first locking portion or post member **96** may be arranged generally parallel to the central longitudinal axis of the expandable anchor member **70** and/or the medical or replacement heart valve implant **16**.

The longitudinally-oriented passageway **98** may be configured to receive the distal portion of the at least one actuator element **15** and/or the external threads **86** therein. The longitudinally-oriented passageway **98** may include internal threads corresponding to the external threads **86** of the actuator element **15**. In some embodiments, the distal portion of the actuator element **15** may be rotatably disposed within the longitudinally-oriented passageway **98** and/or may be releasably coupled to the first locking portion or post member **96** by rotatably engaging the external threads **86** at, proximate, and/or on the distal portion of the actuator element **15** with the internal threads of the longitudinally-oriented passageway **98**, for example. In some embodiments, at least a portion of the distal portion and/or the external threads **86** of the at least one actuator element **15** may extend into the longitudinally-oriented passageway **98** when the at least one actuator element **15** is engaged with the first locking portion or post member **96**, for example in the elongated "delivery" configuration and/or the "everted" configuration. In some embodiments, the first locking portion or post member **96** may be disposed within the lumen of the medical or replacement heart valve implant **16** and/or the expandable anchor member **70** proximate the distal or inflow end of the medical or replacement heart valve implant **16** and/or the expandable anchor member **70** when the expandable anchor member **70** is in the elongated "delivery" configuration and/or the "everted" configuration. In some embodiments, at least a portion of the first locking portion or post member **96** may be disposed distal of the expandable anchor member **70** when the expandable anchor member **70** is in the elongated "delivery" configuration and/or the "everted" configuration.

In some embodiments, the first locking portion or post member **96** may include one or more laterally-extending bars **97** at a distal end of the first locking portion or post member **96**, the one or more laterally-extending bars **97** configured to engage with a proximal end of each of a pair of commissure posts **72** (e.g., FIG. **2**), thereby limiting and/or preventing relative movement therebetween. In at least some embodiments, the plurality of valve leaflets **68** may be secured to the pair of commissure posts **72** to define the valve leaflet commissure(s). For example, at least one of the plurality of valve leaflets **68** may be attached to the first locking portion or post member **96** via each pair of commissure posts **72**. In some embodiments, two adjacent valve leaflets **68** of the plurality of valve leaflets **68** may be attached to the first locking portion or post member **96** via each pair of commissure posts **72**.

In some embodiments, the first locking portion or post member **96** may include at least one aperture **95** extending generally transverse to the longitudinal axis of the longitudinally-oriented passageway **98** and/or the first locking portion or post member **96**. In some embodiments, the at least one aperture **95** may include or comprise a plurality of apertures **95**, two apertures **95**, three apertures **95**, etc. In some embodiments, the at least one aperture **95** may be disposed proximate a proximal end of the first locking portion or post member **96**. The at least one aperture **95** may each extend through the first locking portion or post member **96** at a non-zero angle relative to the central longitudinal axis of the expandable anchor member **70** and/or the medical or replacement heart valve implant **16**. In at least some embodiments, the at least one aperture **95** may extend transversely and/or laterally through a wall of the first locking portion or post member **96** into the longitudinally-oriented passageway **98**. In some embodiments, the at least one aperture **95** may be generally aligned with and/or parallel to the one or more laterally-extending bars **97**.

In some embodiments, the first locking portion or post member **96** may include a flat side **99** formed in and/or extending longitudinally along a length and/or an outer surface of the first locking portion or post member **96**. In some embodiments, the flat side **99** may extend along an entire length of the first locking portion or post member **96**. As will become apparent, the flat side **99** may serve as an alignment and/or anti-rotation feature with respect to the second locking portion or buckle member **76**. For example, the flat side **99** may prevent relative rotation between the first locking portion or post member **96** and the second locking portion or buckle member **76** when the first locking portion or post member **96** is engaged with the second locking portion or buckle member **76**.

In some embodiments, rotatable and/or threaded engagement of the external threads **86** with the internal threads of the longitudinally-oriented passageway **98** may permit the at least one actuator element **15** to axially translate the first locking portion or post member **96** relative to the second locking portion or buckle member **76**. Some suitable but non-limiting materials for the first locking portion or post member **96**, for example metallic materials or polymeric materials, are described below.

FIG. **5** illustrates an example second locking portion or buckle member **76**. In some embodiments, the second locking portion or buckle member **76** may include a longitudinal channel **74** extending through a body portion **75** of the second locking portion or buckle member **76**. In some embodiments, the second locking portion or buckle member **76** may include a projecting portion **73** at a proximal end of the body portion **75** of the second locking portion or buckle member **76**, the projecting portion **73** being configured to releasably attach the medical or replacement heart valve implant **16** to the medical device system **10** and/or the inner sheath or catheter **14**. In at least some embodiments, the longitudinal channel **74** may have a keyed, directional, or non-round cross-sectional profile or shape configured to

slidably receive the first locking portion or post member **96**. The first locking portion or post member **96** may have a cross-sectional profile or shape corresponding to the keyed, directional, or non-round cross-sectional profile or shape of the longitudinal channel **74**. For example, the longitudinal channel **74** and/or the projecting portion **73** may include a flat surface **71** corresponding to the flat side **99** of the first locking portion or post member **96**. As such, the first locking portion or post member **96** may be non-rotatable relative to the second locking portion or buckle member **76** when the first locking portion or post member **96** is engaged with and/or at least partially disposed within the longitudinal channel **74** of the second locking portion or buckle member **76** and/or when the flat side **99** of the first locking portion or post member **96** is aligned with and/or in facing engagement with the flat surface **71** of the second locking portion or buckle member **76**.

In some embodiments, the body portion **75** of the second locking portion or buckle member **76** of each of the at least one locking mechanism **58** may include at least one spring arm **77** configured to deflect laterally and/or circumferentially relative to the central longitudinal axis of the expandable anchor member **70** and/or the medical or replacement heart valve implant **16**. As will become more evident from the discussion below, the ramp **88** of the at least one actuator element **15** may be configured to deflect each of the at least one spring arm **77** laterally and/or circumferentially as the ramp **88** (and the first locking portion or post member **96** engaged thereto) is longitudinally translated through the longitudinal channel **74** of the body portion **75** of the second locking portion or buckle member **76**. In some embodiments, the at least one spring arm **77** may be biased or self-biased toward a neutral position aligned with the body portion **75** and/or may be biased or self-biased into the longitudinal channel **74**.

Briefly referencing FIG. **4** above, the first locking portion or post member **96** includes at least one aperture **95** corresponding to each of the at least one spring arm **77** of the second locking portion or buckle member **76**. The at least one aperture **95** may be configured to receive a portion of its corresponding spring arm **77** after the at least one actuator element **15** has been disengaged from the at least one locking mechanism **58** and/or the first locking portion or post member **96** and the ramp **88** has been removed proximally from within the longitudinal channel **74**. Each of the at least one spring arm **77** is configured to limit or prevent distal movement and/or axial translation of the first locking portion or post member **96** relative to the second locking portion or buckle member **76** in the "deployed" configuration after the at least one actuator element **15** has been disengaged from the at least one locking mechanism **58** and/or the first locking portion or post member **96**, and the ramp **88** has been removed proximally from within the longitudinal channel **74**. Some suitable but non-limiting materials for the second locking portion or buckle member **76**, for example metallic materials or polymeric materials, are described below.

Returning to FIG. **2**, in some embodiments, attachment between the medical or replacement heart valve implant **16** and the inner sheath or catheter **14** may be effected through the use of a coupler **78**. The coupler **78** may generally include a base (not shown) that may be attached to a distal end of the inner sheath or catheter **14**. Projecting distally from the base is a plurality of fingers **79** (e.g., two, three, four, etc.) that are each configured to engage with the medical or replacement heart valve implant **16** at the projecting portion **73** of the second locking portion or buckle member **76** of each of the at least one locking mechanism **58**. In some embodiments, each of the plurality of fingers **79** may extend from the base and/or the distal end of the inner sheath or catheter **14** to the medical or replacement heart valve implant **16**. In some embodiments, each finger **79** may include a collar **80** slidably disposed about the respective finger **79** and the projecting portion **73** of its respective second locking portion or buckle member **76**. A guide **82** may be disposed over each of the fingers **79** proximal of the collar **80** and may serve to keep the fingers **79** of the coupler **78** associated with their respective actuator element **15** extending adjacent to (and axially slidable relative to) the fingers **79** of the coupler **78**.

During delivery, the medical or replacement heart valve implant **16** may be secured at the distal end of the coupler **78** and/or the inner sheath or catheter **14** by two elongated tines of the finger **79** of the coupler **78** being matingly coupled with the projecting portion **73** of the second locking portion or buckle member **76** by the collar **80**, and by the at least one actuator element **15** being coupled to its corresponding first locking portion or post member **96**. When the medical or replacement heart valve implant **16** is advanced within the anatomy to the area of interest, the outer sheath **12** may be translated and/or actuated proximally to expose the medical or replacement heart valve implant **16**. Then, the at least one actuator element **15** can be actuated (e.g., proximally retracted) to axially shorten and/or radially expand the medical or replacement heart valve implant **16** and/or the expandable anchor member **70** from the "delivery" configuration toward the "deployed" configuration by proximally retracting and/or translating the at least one actuator element **15** to pull the first locking portion or post member **96** into engagement with the second locking portion or buckle member **76**, using the handle **18** for example. After verifying satisfactory placement of the medical or replacement heart valve implant **16**, such as by an appropriate imaging technique, the at least one actuator element **15** may each be rotated relative to and decoupled from the first locking portion or post member **96**, which allows the distal portion of the at least one actuator element **15** to be pulled proximally out of the second locking portion or buckle member **76**, where the ramp **88** subsequently engages the collar **80** and thereby retracts the collar **80** from the two elongated tines and the projecting portion **73**. Once the collar **80** has been retracted, the two elongated tines decouple from the projecting portion **73**, and the finger **79** of the coupler **78** may be withdrawn from the medical or replacement heart valve implant **16** thereby leaving the medical or replacement heart valve implant **16** (and/or the expandable anchor member **70**) in the anatomy at the area of interest in a "released" configuration.

FIGS. **6-12** illustrate selected components of an example locking mechanism **58** configured to reversibly lock the medical or replacement heart valve implant **16** (and/or the expandable anchor member **70**) in the "deployed" configuration and/or the "released" configuration, and the general operation of those components. For simplicity and clarity purposes, only one actuator element **15**, first locking portion or post member **96**, second locking portion or buckle member **76**, etc. is shown and discussed (the whole medical or replacement heart valve implant **16** is not shown to facilitate understanding of the locking mechanism(s) **58**). However, it will be understood that the following discussion may apply equally to any and/or all of the components for which there are more than one within the medical or replacement heart valve implant **16** (i.e., the at least one actuator element **15**, the second locking portion or buckle member **76**, the first

locking portion or post member **96**, etc.) and/or the medical device system **10**, unless explicitly stated to the contrary.

As seen in FIGS. **6-12**, each of the at least one actuator element **15** extends through a guide **82** adjacent to and surrounding the finger **79** of the coupler **78**, through the collar **80**, through the second locking portion or buckle member **76**, and into engagement with the first locking portion or post member **96**. For example, the actuator element **15** of the at least one actuator element **15** (e.g., the plurality of actuator elements **15**) corresponding to each of the at least one locking mechanism **58** (e.g., the plurality of locking mechanisms **58**) extends longitudinally through the second locking portion or buckle member **76** of its respective locking mechanism **58** in the "delivery" configuration.

The at least one actuator element **15** may be axially and/or rotatably translatable through and/or relative to the guide **82**, the collar **80**, and/or the second locking portion or buckle member **76**. The at least one actuator element **15** may be rotatable within the longitudinally-oriented passageway **98** of the first locking portion or post member **96**. As discussed above, the distal portion of the at least one actuator element **15** may include external threads **86** configured to rotatably engage and/or extend into the longitudinally-oriented passageway **98** of the first locking portion or post member **96**.

The external threads **86** may releasably couple the distal portion of the at least one actuator element **15** to the first locking portion or post member **96** and form a configuration of these structures that can be utilized during delivery of the medical or replacement heart valve implant **16**. As can be appreciated, a proximal end of the first locking portion or post member **96** and a distal end of the second locking portion or buckle member **76** may be longitudinally separated and/or spaced apart (as seen in FIGS. **6-7**, for example) and, accordingly, the medical or replacement heart valve implant **16** and/or the expandable anchor member **70** may be in an elongated and generally low-profile "delivery" configuration suitable for percutaneous translation through a patient's anatomy to the area of interest (e.g., the native heart valve). In at least some embodiments, the first locking portion or post member **96** and the second locking portion or buckle member **76** may be longitudinally moveable and/or translatable relative to each other in the "delivery" configuration.

When the medical or replacement heart valve implant **16** reaches the area of interest within the anatomy, a clinician can actuate (e.g., proximally retract) the at least one actuator element **15**, for example using the handle **18**, thereby moving and/or translating the proximal end of the first locking portion or post member **96** toward the distal end of the second locking portion or buckle member **76** and into the longitudinal channel **74** of the second locking portion or buckle member **76** in order to axially shorten and/or radially expand the expandable anchor member **70** and/or the medical or replacement heart valve implant **16** towards the "deployed" configuration. Ultimately, the at least one actuator element **15** can be retracted sufficiently far enough to translate the ramp **88** of the at least one actuator element **15** past the at least one spring arm **77** of the second locking portion or buckle member **76** as the ramp **88** passes through the longitudinal channel **74** of the second locking portion or buckle member **76**, thereby displacing and/or deflecting the at least one spring arm **77** laterally and/or circumferentially away from the longitudinal channel **74** of the second locking portion or buckle member **76**, wherein the medical or replacement heart valve implant **16** and/or the expandable anchor member **70** is at an axial and/or longitudinal position (along and/or relative to the central longitudinal axis of the expandable anchor member **70**) corresponding to the "deployed" configuration (as seen in FIGS. **8-9**, for example), suitable for implantation within the anatomy at the area of interest.

In some embodiments, axial translation of the at least one actuator element **15** in a first (e.g., proximal) direction may actuate the expandable anchor member **70** from the "delivery" configuration toward the "deployed" configuration. As mentioned above, in some embodiments, the at least one actuator element **15** may include a ramp **88** extending laterally and/or radially outward from the elongated rod **84**. In some embodiments, the ramp **88** of the at least one actuator element **15** may be configured to prevent the at least one spring arm **77** of the second locking portion or buckle member **76** from engaging the at least one aperture **95** of the first locking portion or post member **96** prior to decoupling the at least one actuator element **15** from the first locking portion or post member **96**, as seen in FIGS. **8-9** for example. At this point in the deployment process, proper positioning of the medical or replacement heart valve implant **16** at the area of interest may be verified using a suitable imaging technique.

In some embodiments and/or some procedures, it may be desirable to remove and/or reposition the medical or replacement heart valve implant **16** and/or expandable anchor member **70**. To do so, a clinician may urge and/or translate the at least one actuator element **15** in a second (e.g., distal) direction to extend and/or elongate the expandable anchor member **70** back towards the "delivery" configuration. Axial translation of the at least one actuator element **15** in the second (e.g., distal) direction relative to the at least one locking mechanism **58** (e.g., the first locking portion or post member **96** and/or the second locking portion or buckle member **76**) may slidably engage the ramp **88** of the at least one actuator element **15** with the at least one spring arm **77** of the second locking portion or buckle member **76**, thereby deflecting the at least one spring arm **77** of the second locking portion or buckle member **76** away from the longitudinal actuator axis of the at least one actuator element **15** and/or laterally or circumferentially relative to the central longitudinal axis of the expandable anchor member **70**, and permitting the first locking portion or post member **96** to pass back through and/or out of the longitudinal channel **74** of the second locking portion or buckle member **76**.

Alternatively, if a clinician is satisfied with the positioning of the medical or replacement heart valve implant **16** (e.g., after visualization of the medical or replacement heart valve implant **16** via a suitable imaging technique), the at least one actuator element **15** may be further actuated (e.g., rotated relative to the first locking portion or post member **96**) to decouple the external threads **86** and/or the at least one actuator element **15** from the internal threads of the first locking portion or post member **96**, as seen in FIGS. **10-11** for example. Rotation of the at least one actuator element **15** relative to the at least one locking mechanism **58** (e.g., the first locking portion or post member **96** and/or the second locking portion or buckle member **76**), the expandable anchor member **70**, the medical or replacement heart valve implant **16**, etc. in the "deployed" configuration may disengage the at least one actuator element **15** from the at least one locking mechanism **58** (e.g., the first locking portion or post member **96** and/or the second locking portion or buckle member **76**) and release the medical or replacement heart valve implant **16**.

Once the at least one actuator element **15** has been disengaged and/or detached from the first locking portion or post member **96**, and the ramp **88** has been axially translated

away from the at least one locking mechanism **58** (e.g., the first locking portion or post member **96** and/or the second locking portion or buckle member **76**), the at least one spring arm **77** of the second locking portion or buckle member **76** extends at least partially into the at least one aperture **95** of the first locking portion or post member **96** and locks the medical or replacement heart valve implant **16** and/or the expandable anchor member **70** in the "deployed" configuration, as seen in FIGS. **10-11** for example, thereby limiting and/or preventing distal movement and/or axial translation of the first locking portion or post member **96** relative to the second locking portion or buckle member **76**.

Further actuation and/or retraction of the at least one actuator element **15** may cause the ramp **88** of the at least one actuator element **15** to engage the collar **80** and pull/slide the collar **80** proximally along the finger **79** while further withdrawing the at least one actuator element **15** from the first locking portion or post member **96**. In doing so, the two elongated tines of the finger **79** may be exposed, as seen in FIG. **10**, and decoupled from the projecting portion **73** of the second locking portion or buckle member **76**, as seen in FIG. **12**. Withdrawal of the at least one actuator element **15** completely from the first locking portion or post member **96** releases the expandable anchor member **70** from the at least one actuator element **15** and leaves the medical or replacement heart valve implant **16** disposed at the area of interest in the "released" configuration.

The materials that can be used for the various components of the medical device system **10**, the outer sheath **12**, the inner sheath or catheter **14**, the medical or replacement heart valve implant **16**, the handle **18**, etc. (and/or other systems disclosed herein) and the various elements thereof disclosed herein may include those commonly associated with medical devices. For simplicity purposes, the following discussion makes reference to the medical device system **10**, the outer sheath **12**, the inner sheath or catheter **14**, the medical or replacement heart valve implant **16**, the handle **18**, etc. However, this is not intended to limit the devices and methods described herein, as the discussion may be applied to other elements, members, components, or devices disclosed herein, such as, but not limited to, the actuator elements **15**, the seal member **20**, the valve leaflets **68**, the expandable anchor member **70**, the commissure posts **72**, the second locking portion or buckle members **76**, the collars **80**, the guides **82**, the first locking portion or post member **96**, etc., and/or elements or components thereof.

In some embodiments, the medical device system **10**, the outer sheath **12**, the inner sheath or catheter **14**, the medical or replacement heart valve implant **16**, the handle **18**, etc., and/or components thereof (such as, but not limited to, the actuator elements **15**, the seal member **20**, the valve leaflets **68**, the expandable anchor member **70**, the commissure posts **72**, the second locking portion or buckle members **76**, the collars **80**, the guides **82**, the first locking portion or post member **96**, etc.), may be made from a metal, metal alloy, polymer (some examples of which are disclosed below), a metal-polymer composite, ceramics, combinations thereof, and the like, or other suitable material. Some examples of suitable metals and metal alloys include stainless steel, such as 444V, 444L, and 314LV stainless steel; mild steel; nickel-titanium alloy such as linear-elastic and/or super-elastic nitinol; other nickel alloys such as nickel-chromium-molybdenum alloys (e.g., UNS: N06625 such as INCONEL® 625, UNS: N06022 such as HASTELLOY® C-22®, UNS: N10276 such as HASTELLOY® C276®, other HASTELLOY® alloys, and the like), nickel-copper alloys (e.g., UNS: N04400 such as MONEL® 400, NICKELVAC® 400, NICORROS® 400, and the like), nickel-cobalt-chromium-molybdenum alloys (e.g., UNS: R44035 such as MP35-N® and the like), nickel-molybdenum alloys (e.g., UNS: N10665 such as HASTELLOY® ALLOY B2®), other nickel-chromium alloys, other nickel-molybdenum alloys, other nickel-cobalt alloys, other nickel-iron alloys, other nickel-copper alloys, other nickel-tungsten or tungsten alloys, and the like; cobalt-chromium alloys; cobalt-chromium-molybdenum alloys (e.g., UNS: R44003 such as ELGILOY®, PHYNOX®, and the like); platinum enriched stainless steel; titanium; platinum; palladium; gold; combinations thereof; and the like; or any other suitable material.

As alluded to herein, within the family of commercially available nickel-titanium or nitinol alloys, is a category designated "linear elastic" or "non-super-elastic" which, although may be similar in chemistry to conventional shape memory and super elastic varieties, may exhibit distinct and useful mechanical properties. Linear elastic and/or non-super-elastic nitinol may be distinguished from super elastic nitinol in that the linear elastic and/or non-super-elastic nitinol does not display a substantial "superelastic plateau" or "flag region" in its stress/strain curve like super elastic nitinol does. Instead, in the linear elastic and/or non-super-elastic nitinol, as recoverable strain increases, the stress continues to increase in a substantially linear, or a somewhat, but not necessarily entirely linear relationship until plastic deformation begins or at least in a relationship that is more linear than the super elastic plateau and/or flag region that may be seen with super elastic nitinol. Thus, for the purposes of this disclosure linear elastic and/or non-super-elastic nitinol may also be termed "substantially" linear elastic and/or non-super-elastic nitinol.

In some cases, linear elastic and/or non-super-elastic nitinol may also be distinguishable from super elastic nitinol in that linear elastic and/or non-super-elastic nitinol may accept up to about 2-5% strain while remaining substantially elastic (e.g., before plastically deforming) whereas super elastic nitinol may accept up to about 8% strain before plastically deforming. Both of these materials can be distinguished from other linear elastic materials such as stainless steel (that can also be distinguished based on its composition), which may accept only about 0.2 to 0.44 percent strain before plastically deforming.

In some embodiments, the linear elastic and/or non-super-elastic nickel-titanium alloy is an alloy that does not show any martensite/austenite phase changes that are detectable by differential scanning calorimetry (DSC) and dynamic metal thermal analysis (DMTA) analysis over a large temperature range. For example, in some embodiments, there may be no martensite/austenite phase changes detectable by DSC and DMTA analysis in the range of about −60 degrees Celsius (° C.) to about 120° C. in the linear elastic and/or non-super-elastic nickel-titanium alloy. The mechanical bending properties of such material may therefore be generally inert to the effect of temperature over this very broad range of temperature. In some embodiments, the mechanical bending properties of the linear elastic and/or non-super-elastic nickel-titanium alloy at ambient or room temperature are substantially the same as the mechanical properties at body temperature, for example, in that they do not display a super-elastic plateau and/or flag region. In other words, across a broad temperature range, the linear elastic and/or non-super-elastic nickel-titanium alloy maintains its linear elastic and/or non-super-elastic characteristics and/or properties.

In some embodiments, the linear elastic and/or non-superelastic nickel-titanium alloy may be in the range of about 50 to about 60 weight percent nickel, with the remainder being essentially titanium. In some embodiments, the composition is in the range of about 54 to about 57 weight percent nickel. One example of a suitable nickel-titanium alloy is FHP-NT alloy commercially available from Furukawa Techno Material Co. of Kanagawa, Japan. Other suitable materials may include ULTANIUM™ (available from Neo-Metrics) and GUM METAL™ (available from Toyota). In some other embodiments, a superelastic alloy, for example a superelastic nitinol can be used to achieve desired properties.

In at least some embodiments, portions or all of the medical device system **10**, the outer sheath **12**, the inner sheath or catheter **14**, the medical or replacement heart valve implant **16**, the handle **18**, etc., and/or components thereof, may also be doped with, made of, or otherwise include a radiopaque material. Radiopaque materials are understood to be materials capable of producing a relatively bright image on a fluoroscopy screen or another imaging technique during a medical procedure. This relatively bright image aids a user in determining the location of the medical device system **10**, the outer sheath **12**, the inner sheath or catheter **14**, the medical or replacement heart valve implant **16**, the handle **18**, etc. Some examples of radiopaque materials can include, but are not limited to, gold, platinum, palladium, tantalum, tungsten alloy, polymer material loaded with a radiopaque filler, and the like. Additionally, other radiopaque marker bands and/or coils may also be incorporated into the design of the medical device system **10**, the outer sheath **12**, the inner sheath or catheter **14**, the medical or replacement heart valve implant **16**, the handle **18**, etc. to achieve the same result.

In some embodiments, a degree of Magnetic Resonance Imaging (MRI) compatibility is imparted into the medical device system **10**, the outer sheath **12**, the inner sheath or catheter **14**, the medical or replacement heart valve implant **16**, the handle **18**, etc. For example, the medical device system **10**, the outer sheath **12**, the inner sheath or catheter **14**, the medical or replacement heart valve implant **16**, the handle **18**, etc., and/or components or portions thereof, may be made of a material that does not substantially distort the image and create substantial artifacts (e.g., gaps in the image). Certain ferromagnetic materials, for example, may not be suitable because they may create artifacts in an MRI image. The medical device system **10**, the outer sheath **12**, the inner sheath or catheter **14**, the medical or replacement heart valve implant **16**, the handle **18**, etc., or portions thereof, may also be made from a material that the MRI machine can image. Some materials that exhibit these characteristics include, for example, tungsten, cobalt-chromium-molybdenum alloys (e.g., UNS: R44003 such as ELGILOY®, PHYNOX®, and the like), nickel-cobalt-chromium-molybdenum alloys (e.g., UNS: R44035 such as MP35-N® and the like), nitinol, and the like, and others.

In some embodiments, the medical device system **10**, the outer sheath **12**, the inner sheath or catheter **14**, the medical or replacement heart valve implant **16**, the handle **18**, etc., and/or portions thereof, may be made from or include a polymer or other suitable material. Some examples of suitable polymers may include polytetrafluoroethylene (PTFE), ethylene tetrafluoroethylene (ETFE), fluorinated ethylene propylene (FEP), polyoxymethylene (POM, for example, DELRIN® available from DuPont), polyether block ester, polyurethane (for example, Polyurethane 85A), polypropylene (PP), polyvinylchloride (PVC), polyether-ester (for example, ARNITEL® available from DSM Engineering Plastics), ether or ester based copolymers (for example, butylene/poly(alkylene ether) phthalate and/or other polyester elastomers such as HYTREL® available from DuPont), polyamide (for example, DURETHAN® available from Bayer or CRISTAMID® available from Elf Atochem), elastomeric polyamides, block polyamide/ethers, polyether block amide (PEBA, for example available under the trade name PEBAX®), ethylene vinyl acetate copolymers (EVA), silicones, polyethylene (PE), Marlex high-density polyethylene, Marlex low-density polyethylene, linear low density polyethylene (for example REXELL®), polyester, polybutylene terephthalate (PBT), polyethylene terephthalate (PET), polytrimethylene terephthalate, polyethylene naphthalate (PEN), polyetheretherketone (PEEK), polyimide (PI), polyetherimide (PEI), polyphenylene sulfide (PPS), polyphenylene oxide (PPO), poly paraphenylene terephthalamide (for example, KEVLAR®), polysulfone, nylon, nylon-12 (such as GRILAMID® available from EMS American Grilon), perfluoro(propyl vinyl ether) (PFA), ethylene vinyl alcohol, polyolefin, polystyrene, epoxy, polyvinylidene chloride (PVdC), poly(styrene-b-isobutylene-b-styrene) (for example, SIBS and/or SIBS 50A), polycarbonates, ionomers, polyurethane silicone copolymers (for example, ElastEon® from Aortech Biomaterials or ChronoSil® from AdvanSource Biomaterials), biocompatible polymers, other suitable materials, or mixtures, combinations, copolymers thereof, polymer/metal composites, and the like. In some embodiments the sheath can be blended with a liquid crystal polymer (LCP). For example, the mixture can contain up to about 6 percent LCP.

In some embodiments, the medical device system **10**, the outer sheath **12**, the inner sheath or catheter **14**, the medical or replacement heart valve implant **16**, the handle **18**, etc. and/or other elements disclosed herein may include a fabric material disposed over or within the structure. The fabric material may be composed of a biocompatible material, such a polymeric material or biomaterial, adapted to promote tissue ingrowth. In some embodiments, the fabric material may include a bioabsorbable material. Some examples of suitable fabric materials include, but are not limited to, polyethylene glycol (PEG), nylon, polytetrafluoroethylene (PTFE, ePTFE), a polyolefinic material such as a polyethylene, a polypropylene, polyester, polyurethane, and/or blends or combinations thereof.

In some embodiments, the medical device system **10**, the outer sheath **12**, the inner sheath or catheter **14**, the medical or replacement heart valve implant **16**, the handle **18**, etc. may include and/or be formed from a textile material. Some examples of suitable textile materials may include synthetic yarns that may be flat, shaped, twisted, textured, pre-shrunk or un-shrunk. Synthetic biocompatible yarns suitable for use in the present invention include, but are not limited to, polyesters, including polyethylene terephthalate (PET) polyesters, polypropylenes, polyethylenes, polyurethanes, polyolefins, polyvinyls, polymethylacetates, polyamides, naphthalene dicarboxylene derivatives, natural silk, and polytetrafluoroethylenes. Moreover, at least one of the synthetic yarns may be a metallic yarn or a glass or ceramic yarn or fiber. Useful metallic yarns include those yarns made from or containing stainless steel, platinum, gold, titanium, tantalum or a Ni—Co—Cr-based alloy. The yarns may further include carbon, glass or ceramic fibers. Desirably, the yarns are made from thermoplastic materials including, but not limited to, polyesters, polypropylenes, polyethylenes, polyurethanes, polynaphthalenes, polytetrafluoroethylenes, and the like. The yarns may be of the multifilament, monofilament, or spun-types. The type and denier of the yarn

chosen may be selected in a manner which forms a biocompatible and implantable prosthesis and, more particularly, a vascular structure having desirable properties.

In some embodiments, the medical device system **10**, the outer sheath **12**, the inner sheath or catheter **14**, the medical or replacement heart valve implant **16**, the handle **18**, etc. may include and/or be treated with a suitable therapeutic agent. Some examples of suitable therapeutic agents may include anti-thrombogenic agents (such as heparin, heparin derivatives, urokinase, and PPack (dextrophenylalanine proline arginine chloromethylketone)); anti-proliferative agents (such as enoxaparin, angiopeptin, monoclonal antibodies capable of blocking smooth muscle cell proliferation, hirudin, and acetylsalicylic acid); anti-inflammatory agents (such as dexamethasone, prednisolone, corticosterone, budesonide, estrogen, sulfasalazine, and mesalamine); anti-neoplastic/antiproliferative/anti-mitotic agents (such as paclitaxel, 5-fluorouracil, cisplatin, vinblastine, vincristine, epothilones, endostatin, angiostatin and thymidine kinase inhibitors); anesthetic agents (such as lidocaine, bupivacaine, and ropivacaine); anti-coagulants (such as D-Phe-Pro-Arg chloromethyl keton, an RGD peptide-containing compound, heparin, anti-thrombin compounds, platelet receptor antagonists, anti-thrombin antibodies, anti-platelet receptor antibodies, aspirin, prostaglandin inhibitors, platelet inhibitors, and tick antiplatelet peptides); vascular cell growth promoters (such as growth factor inhibitors, growth factor receptor antagonists, transcriptional activators, and translational promoters); vascular cell growth inhibitors (such as growth factor inhibitors, growth factor receptor antagonists, transcriptional repressors, translational repressors, replication inhibitors, inhibitory antibodies, antibodies directed against growth factors, bifunctional molecules consisting of a growth factor and a cytotoxin, bifunctional molecules consisting of an antibody and a cytotoxin); cholesterol-lowering agents; vasodilating agents; and agents which interfere with endogenous vascoactive mechanisms.

It should be understood that this disclosure is, in many respects, only illustrative. Changes may be made to details, particularly in matters of shape, size, and arrangement of steps, without exceeding the scope of the invention. This may include, to the extent that it is appropriate, the use of any of the features of one example embodiment being used in other embodiments. The invention's scope is, of course, defined in the language in which the appended claims are expressed.

What is claimed is:

1. A medical device system, comprising:

a replacement heart valve implant including an expandable anchor member reversibly actuatable between a delivery configuration and a deployed configuration;

wherein the replacement heart valve implant includes at least one locking mechanism configured to lock the expandable anchor member in the deployed configuration,

wherein the at least one locking mechanism comprises a first locking portion secured to the expandable anchor member and a second locking portion secured to the expandable anchor member, the first locking portion and the second locking portion being longitudinally movable relative to each other in the delivery configuration,

wherein the second locking portion comprises at least one spring arm configured to deflect circumferentially relative to a central longitudinal axis of the expandable anchor member; and

at least one actuator element configured to releasably engage the at least one locking mechanism and actuate the expandable anchor member between the delivery configuration and the deployed configuration;

wherein the at least one actuator element includes external threads on a distal portion of each actuator element and a ramp disposed proximal of the external threads.

2. The medical device system of claim **1**, wherein the first locking portion is non-releasably secured to a distal portion of the expandable anchor member, and the second locking portion is fixedly secured to a proximal portion of the expandable anchor member.

3. The medical device system of claim **1**, wherein the second locking portion is configured to slidably receive the first locking portion within a longitudinal channel extending through the second locking portion.

4. The medical device system of claim **3**, wherein the first locking portion is non-rotatable relative to the second locking portion when the first locking portion is at least partially disposed within the longitudinal channel.

5. The medical device system of claim **1**, wherein the first locking portion includes a longitudinally-oriented passageway extending at least partially through the first locking portion, the longitudinally-oriented passageway being configured to receive the distal portion of the at least one actuator element.

6. The medical device system of claim **5**, wherein the longitudinally-oriented passageway includes internal threads corresponding to the external threads.

7. The medical device system of claim **1**, wherein the ramp is configured to deflect each of the at least one spring arm circumferentially as the ramp is longitudinally translated through the second locking portion.

8. The medical device system of claim **1**, wherein the first locking portion includes at least one aperture corresponding to each of the at least one spring arm, the at least one aperture extending through the first locking portion at a non-zero angle relative to the central longitudinal axis and being configured to receive a portion of its corresponding spring arm.

9. The medical device system of claim **1**, wherein each of the at least one spring arm is configured to prevent distal movement of the first locking portion relative to the second locking portion after the at least one actuator element has been disengaged from the at least one locking mechanism.

10. A medical device system, comprising:

an outer sheath;

a handle disposed at a proximal end of the outer sheath;

a replacement heart valve implant including an expandable anchor member reversibly actuatable between a delivery configuration and a deployed configuration;

wherein the replacement heart valve implant includes at least one locking mechanism configured to lock the expandable anchor member in the deployed configuration; and

at least one actuator element configured to releasably engage the at least one locking mechanism and actuate the expandable anchor member between the delivery configuration and the deployed configuration;

wherein the at least one actuator element includes external threads on a distal portion of each actuator element and a ramp disposed proximal of the external threads;

wherein the at least one actuator element extends from the handle to the replacement heart valve implant, the replacement heart valve implant being disposed at a distal end of the outer sheath.

11. The medical device system of claim 10, wherein the at least one actuator element is configured to reversibly actuate the expandable anchor member between the delivery configuration and the deployed configuration while the at least one actuator element is engaged with the at least one locking mechanism.

12. The medical device system of claim 10, wherein the handle is configured to rotate each of the at least one actuator element relative to the at least one locking mechanism in the deployed configuration.

13. The medical device system of claim 12, wherein rotation of the at least one actuator element relative to the at least one locking mechanism in the deployed configuration disengages the at least one actuator element from the at least one locking mechanism and releases the replacement heart valve implant.

14. A medical device system, comprising:

an outer sheath;

a handle disposed at a proximal end of the outer sheath;

a replacement heart valve implant including an expandable anchor member reversibly actuatable between a delivery configuration and a deployed configuration;

wherein the replacement heart valve implant includes a plurality of locking mechanisms configured to lock the expandable anchor member in the deployed configuration; and

a plurality of actuator elements corresponding to the plurality of locking mechanisms, the plurality of actuator elements being configured to releasably engage the plurality of locking mechanisms and actuate the expandable anchor member between the delivery configuration and the deployed configuration;

wherein the plurality of actuator elements includes external threads proximate a distal end of each actuator element and a ramp disposed proximal of the external threads;

wherein the plurality of actuator elements extends from the handle to the replacement heart valve implant, the replacement heart valve implant being disposed at a distal end of the outer sheath.

15. The medical device system of claim 14, wherein the expandable anchor member is tubular and defines a lumen extending coaxially along a central longitudinal axis of the replacement heart valve implant.

16. The medical device system of claim 14, wherein the handle is configured to rotate each of the plurality of actuator elements relative to the outer sheath in the deployed configuration.

17. The medical device system of claim 16, wherein each of the plurality of actuator elements defines its own longitudinal actuator axis and is configured to rotate about its own longitudinal actuator axis.

18. The medical device system of claim 17, wherein the plurality of locking mechanisms each comprise:

a first locking portion secured to the expandable anchor member and having at least one valve leaflet attached to the first locking portion; and

a second locking portion secured to the expandable anchor member;

wherein the actuator element of the plurality of actuator elements corresponding to each of the plurality of locking mechanisms extends longitudinally through the second locking portion of its locking mechanism in the delivery configuration,

the first locking portion and the second locking portion being longitudinally movable relative to each other in the delivery configuration,

wherein the second locking portion comprises at least one spring arm configured to deflect circumferentially relative to a central longitudinal axis of the expandable anchor member.

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